UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ALLSTATE INSURANCE COMPANY; ALLSTATE INDEMNITY COMPANY; ALLSTATE PROPERTY AND CASUALTY INSURANCE COMPANY; ALLSTATE NEW JERSEY INSURANCE COMPANY; ALLSTATE NEW JERSEY PROPERTY AND CASUALTY INSURANCE COMPANY; ALLSTATE FIRE AND CASUALTY INSURANCE COMPANY; ENCOMPASS INDEMNITY COMPANY; ENCOMPASS HOME AND AUTO INSURANCE COMPANY; and ENCOMPASS INSURANCE COMPANY OF NEW JERSEY, Plaintiffs, v. AMERITOX, LTD.; RONALD C. BACKER, Ph.D.; HARRY L. LEIDER, M.D.; A. SCOTT WALTON; ANCELMO E. LOPES; and JAY B. ZIMMERMAN, Defendants.	Civil Action No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs Allstate Insurance Company, Allstate Indemnity Company, Allstate Property and Casualty Insurance Company, Allstate New Jersey Insurance Company, Allstate New Jersey Property and Casualty Insurance Company, Allstate Fire and Casualty Insurance Company, Encompass Indemnity Company, Encompass Home and Auto Insurance Company, and Encompass Insurance Company of New Jersey (collectively, "Allstate" and/or "plaintiffs"), by their attorneys SMITH & BRINK, P.C., hereby allege as follows.

I. INTRODUCTION

1. This is a case about one of the largest clinical urine drug testing laboratories in the country and its managers/operators who engaged in a wide-ranging and comprehensive scheme to defraud Allstate by submitting, or causing to be submitted, false and fraudulent lab reports, medical records, bills, and invoices through the U.S. Mail seeking reimbursement under the No-Fault laws of several States for urine drug testing services that were never performed, were medically unnecessary, and/or were submitted using fraudulent billing practices.

2. Ameritox, Ltd. ("Ameritox"); its former Vice President of Toxicology, Ronald C. Backer, Ph.D. ("Backer"); its Chief Medical Officer and Senior Vice President, Harry L. Leider, M.D. ("Leider"); its current Chief Executive Officer, A. Scott Walton ("Walton"); its former Chief Executive Officer and current Vice Chairman and Special Advisor, Ancelmo E. Lopes ("Lopes"); and its former Chief Operating Officer and current Chief Laboratory Officer and Senior Vice President, Jay B. Zimmerman ("Zimmerman") (collectively, the "defendants") conspired to, and did in fact, defraud Allstate by perpetrating a healthcare billing fraud scheme in violation of state and federal law.

3. The purpose of the fraudulent scheme executed by the defendants was to generate claims to, and collect payment from, Allstate pursuant to the No-Fault laws of the States of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky for the purported treatment of patients who were prescribed pain medication resulting from involvement in a motor vehicle accident.

4. Ameritox purports to provide urine drug testing services to referring providers whose patients are being prescribed medication (1) to ensure that the provider's patients are

complying with their medication regime and/or (2) to ensure that the provider's patients are not abusing their prescription medication or illicit drugs.

5. In reality, the defendants encouraged and actively sought to generate as many referrals as possible regardless of the reason for the referral and without a determination from the treating provider that each urine drug test performed was necessary for each patient.

6. To achieve their fraudulent objective, the defendants engaged in a comprehensive scheme involving kickbacks, aggressive sales representatives and sales tactics, and false advertising designed to obtain as many referrals of urine specimens for drug testing to Ameritox as possible.

7. The managers and operators of Ameritox, including Backer, Leider, Walton, Lopes, and Zimmerman, conspired to develop a systematic plan that enabled Ameritox to submit claims to Allstate for urine drug testing that was medically unnecessary and fraudulently billed.

8. The singular purpose of the defendants' scheme was to exploit the No-Fault benefits available in New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky by generating as many bills as possible by doing (or purporting to do) as much urine drug testing as possible.

9. To this end, the defendants engaged in a number of improper practices to maximize referrals, including kickbacks, false advertising, acute pressure from sales representatives applied to referring providers, and the use of panel preferences and preprinted forms that ignored questions of medical necessity in favor of preselecting as many urine drug tests as possible.

10. Once urine specimens were referred to Ameritox (through one or more improper ways, as referenced in the preceding paragraph and as detailed *infra*), Ameritox billed for

confirmatory urine drug testing that was not necessary and was done in violation of the established standard of care in the clinical laboratory community.

11. Ameritox also billed for duplicative urine drug screening that was likewise not necessary.

12. Finally, Ameritox utilized a number of fraudulent billing practices, including unbundling and billing using codes that are no longer in effect.

13. Billing for services that were not necessary is prohibited under the No-Fault laws of the six States at issue herein.

14. Ameritox is a sophisticated laboratory and one of the largest in the country that tests tens of thousands of urine samples each week.

15. Allstate reasonably relied on Ameritox's bills to contain truthful and accurate representations regarding the urine drug testing allegedly performed and the necessity for the same.

16. Ameritox exploited its superior knowledge of esoteric laboratory practices and billing and took advantage of Allstate's lack of familiarity with the same to bill Allstate for urine drug tests that were never performed and/or were unnecessary.

17. All of the defendants' actions described throughout this Complaint were undertaken intentionally.

18. The insurance fraud scheme executed by the defendants was designed to, and did in fact, result in payment of No-Fault proceeds from Allstate to Ameritox for the benefit of each and all of the defendants named herein.

19. In each claim at issue in this Complaint for which Allstate is seeking damages, an Allstate automobile insurance contract was the platform upon which the defendants perpetrated their fraudulent scheme.

20. By this Complaint, Allstate brings this action against the defendants for: (1) violations of the federal Racketeer Influenced and Corrupt Organizations (RICO) Act, 18 U.S.C. §1961, *et seq*.; (2) common law fraud; (3) violations of the New Jersey Insurance Fraud Prevention Act, N.J. Stat. Ann 17:33A-1, *et seq*.; (4) violations of the Pennsylvania Insurance Fraud statute, 18 Pa. Cons. Stat. § 4117(a); (5) violations of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq*.; and (6) unjust enrichment.

21. Allstate's claim for compensatory damages include: (1) payments made by Allstate to Ameritox in reliance upon the defendants' false representations that Ameritox was eligible to receive reimbursement under the No-Fault laws at issue herein; (2) payments made by Allstate to Ameritox in reliance upon the false medical documentation submitted, or caused to be submitted, by the defendants; (3) treble damages; (4) statutory interest; (5) costs, including, but not limited to, the costs of claims handling and the cost of investigation to uncover the fraudulent scheme executed by the defendants; and (6) attorney's fees.

22. By this Complaint, Allstate also seeks a declaration pursuant to 28 U.S.C. § 2201 that Ameritox has no right to receive payments from Allstate for any pending and previously-denied claims for urine drug testing services that were not reasonably necessary and/or were not properly billed.

23. As a result of the defendants' fraudulent billing scheme detailed herein, Allstate has paid in excess of $1,283,212 to Ameritox since 2007.

II. THE PARTIES

A. PLAINTIFFS

24. Allstate Insurance Company, Allstate Indemnity Company, Allstate Property and Casualty Insurance Company, Allstate New Jersey Insurance Company, Allstate New Jersey

Property and Casualty Insurance Company, Allstate Fire and Casualty Insurance Company, Encompass Indemnity Company, Encompass Home and Auto Insurance Company, and Encompass Insurance Company of New Jersey are corporations duly organized under the laws of the State of Illinois.

25. Allstate Insurance Company, Allstate Indemnity Company, Allstate Property and Casualty Insurance Company, Allstate Fire and Casualty Insurance Company, Encompass Indemnity Company, and Encompass Home and Auto Insurance Company have their principal places of business in Northbrook, Illinois.

26. Allstate New Jersey Insurance Company, Allstate New Jersey Property and Casualty Insurance Company, and Encompass Insurance Company of New Jersey have their principal places of business in Bridgewater, New Jersey.

27. At all times relevant to this Complaint, Allstate was authorized to conduct business in New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky.

B. DEFENDANTS

1. Ameritox, Ltd.

28. Ameritox, Ltd. is a limited partnership organized under the laws of the State of Texas with its principal place of business at 300 East Lombard Street, Suite 1610, Baltimore, Maryland.

29. At all times relevant to this Complaint, Ameritox purportedly performed urine drug testing of specimens that were collected from patients insured under Allstate policies issued in New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky at laboratories located in Midland, Texas and Greensboro, North Carolina, including those patients identified in Exhibits 1

(New York), 2 (New Jersey), 3 (Michigan), 4 (Pennsylvania), 5 (Florida), and 6 (Kentucky) annexed hereto.

30. Ameritox specifically and intentionally sought to and did in fact transact business in New York, including submitting hundreds of claims to Allstate under New York's statutory No-Fault laws.

2. Ronald C. Backer, Ph.D.

31. Ronald C. Backer, Ph.D. is a resident and citizen of the State of Florida.

32. Backer is a licensed clinical chemistry director in the State of Florida.

33. Backer is the former Vice President of Toxicology at Ameritox.

34. As part of his duties as the Vice President of Toxicology, Backer signed his name to bills requesting payment from Allstate for most of the urine drug testing services Ameritox purportedly rendered.

35. These bills were sent to Allstate via the U.S. Mail.

36. Hundreds of the bills signed by Backer and sent to Allstate arose from claims under New York's statutory No-Fault laws.

37. Backer had knowledge of and approved Ameritox's claims for payment under New York's No-Fault law.

38. As an officer of Ameritox, Backer benefitted from Ameritox's wrongful receipt of New York (and other) No-Fault proceeds from Allstate.

3. Harry L. Leider, M.D.

39. Harry L. Leider, M.D. is a resident and citizen of the State of Illinois.

40. Leider is a medical doctor licensed in the State of Maryland.

41. From September 2008 through April 2013, Leider was the Chief Medical Officer and Senior Vice President of Ameritox.

42. As part of his self-described duties as Chief Medical Officer and Senior Vice President, Leider "was a member of the company's senior management team and played a key role" in "leading [Ameritox's] clinical research program, provider relations strategy, and initiatives within [Ameritox] to create new products and services."

43. Leider had knowledge of and approved Ameritox's claims for payment under New York's No-Fault law.

44. Upon information and belief, Leider was also involved in developing strategy vis-à-vis New York-based referring providers.

45. As an officer of Ameritox, Leider benefitted from Ameritox's wrongful receipt of New York (and other) No-Fault proceeds from Allstate.

4. A. Scott Walton

46. A. Scott Walton is a resident and citizen of the State of Maryland.

47. Walton became Chief Executive Officer of Ameritox in September 2012.

48. As part of his duties as Chief Executive Officer, Walton had knowledge of and approved Ameritox's urine drug testing procedures and billing practices, including in New York.

49. As an officer of Ameritox, Walton benefitted from Ameritox's wrongful receipt of New York (and other) No-Fault proceeds from Allstate.

5. Ancelmo E. Lopes

50. Ancelmo E. Lopes is a resident and citizen of the State of Maryland.

51. Lopes served as Chief Executive Officer of Ameritox from 2007 to September 2012.

52. Since September 2012, Lopes has served as Vice Chairman and Special Advisor to Ameritox.

53. As part of his duties as Chief Executive Officer, Lopes had knowledge of and approved Ameritox's urine drug testing procedures and billing practices.

54. As an officer of Ameritox, Lopes benefitted from Ameritox's wrongful receipt of New York (and other) No-Fault proceeds from Allstate.

6. Jay B. Zimmerman

55. Jay B. Zimmerman is a resident and citizen of the State of Maryland.

56. At all relevant times, Zimmerman served as the Chief Operating Officer and/or Chief Laboratory Officer and Senior Vice President of Ameritox.

57. As part of his duties as the Chief Operating Officer/Chief Laboratory Officer, Zimmerman was directly responsible for implementing the standard operating procedures and practices at Ameritox.

58. Zimmerman has characterized his role at Ameritox as "[p]rovid[ing] overall company leadership" and "develop[ing] laboratory strategy," including implementing laboratory urine drug testing methodologies and protocols.

59. At certain relevant times, Zimmerman was in charge of Ameritox's specimen processor program.

60. Zimmerman had knowledge of and approved Ameritox's claims for payment under New York's No-Fault law and the other States at issue herein.

61. As an officer of Ameritox, Zimmerman benefitted from Ameritox's wrongful receipt of New York (and other) No-Fault proceeds from Allstate.

III. JURISDICTION AND VENUE

62. Subject matter jurisdiction over this action is conferred upon this Court by 28 U.S.C. §§ 1331 and 1332.

63. Supplemental jurisdiction over the plaintiffs' state law claims is proper pursuant to 28 U.S.C. § 1367.

64. Venue is proper pursuant to 28 U.S.C. § 1391(b)(2) whereas a substantial part of the events giving rise to the claims at issue herein occurred within the Eastern District of New York.

65. This Court also has personal jurisdiction over each of the defendants.

66. "[B]oth state and federal courts in New York have found that where a plaintiff has presented a sufficient showing that a conspiracy exists, personal jurisdiction may exist over a defendant based on acts that were committed by his co-conspirators." Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc., 26 F. Supp. 2d 593, 601 (S.D.N.Y. 1998).

67. Pursuant to New York's long-arm statute, "a court may exercise personal jurisdiction over any non-domiciliary, or his executor or administrator, who in person or through an agent . . . commits a tortious act within the state." NY CPLR § 302(a)(2).

68. "[NY CPLR §] 302(a)(2) permits the Court to exercise jurisdiction over an out-of-state defendant if a plaintiff has alleged tortious conduct occurring within New York." Elsevier, Inc. v. Grossman, 77 F. Supp. 3d 331, 345 (S.D.N.Y. 2015).

69. "Personal jurisdiction pursuant to section 302(a)(1) may be satisfied with proof that just one transaction occurred in New York as long as defendants' activities were purposeful and substantially related to plaintiffs' claim." Baron Philippe de Rothschild, S.A. v. Paramount Distillers, Inc., 923 F. Supp. 433, 436 (S.D.N.Y. 1996).

70. The defendants actively marketed to New York providers and billed Allstate in excess of one million dollars for claims arising under New York law related to patients based in New York.

71. Ameritox engaged in purposeful activities in New York by seeking and submitting payment demands for claims made under New York's No-Fault laws (as detailed *infra*). *See, e.g.*, Exhibit 1.

72. Backer, Leider, Walton, Lopes, and Zimmerman knew of, consented to, encouraged, and benefitted from each New York No-Fault transaction because they caused Ameritox sales representatives to work and do business in New York, caused urine specimens to be referred from New York-based treating providers, explicitly sought payments from Allstate under the New York No-Fault laws, and received payments from Allstate under the New York No-Fault laws.

73. Backer signed bills submitted to Allstate as the "treating provider" related to hundreds of claims arising under the New York No-Fault laws.

74. Backer, Leider, Walton, Lopes, and Zimmerman – all executive officers of Ameritox – exercised control over every aspect of Ameritox's business, including the decision to seek referrals of urine samples from patients injured in motor vehicle accidents and eligible for benefits under the New York No-Fault laws.

75. As the leaders of Ameritox whose compensation was tied at least in part on the revenue generated by Ameritox, Backer, Leider, Walton, Lopes, and Zimmerman had financial stakes in Ameritox.

76. They worked to increase the number of urine samples referred to Ameritox (including samples from patients treating in New York), which in turn increased the amount of

urine drug testing for which Ameritox could seek payment, including reimbursement under New York's No-Fault law.

77. Backer, Leider, Walton, Lopes, and Zimmerman were primary actors in causing Ameritox to establish a presence in New York (including through the use of New York-based sales representatives) and causing Ameritox to bill to automobile insurers in New York, including Allstate.

78. The individual defendants' activities in and contacts with New York were purposefully sought and transacted to take advantage of the benefits available under New York's No-Fault laws.

79. As the allegations and causes of action in the within Complaint arise from the defendants' fraudulent demands for payment under the No-Fault laws of New York, amongst other States, there is no question that there is a substantial relationship between the transactions at issue (billing for urine drug testing that was unnecessary and/or which was improperly billed) and Allstate's causes of action.

IV. SUMMARY OF RELEVANT NO-FAULT LAWS

80. No-Fault is a system of motor vehicle insurance whereby a party injured in an automobile accident can recover damages up to a specific amount against his or her own auto insurer regardless of who was responsible for the accident.

81. Relevant to this Complaint, the following states have adopted a form of No-Fault insurance: New York's Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law § 5101, *et seq.*), and the regulations promulgated pursuant thereto (11 NYCCR § 65, *et seq.*) (collectively, "New York No-Fault Law"); New Jersey's Automobile Reparation Reform Act (N.J. Stat. Ann. 39:6A-1, *et seq.*) and New Jersey's Compulsory Insurance Law (N.J. Stat. Ann. 39:6B-

1, *et seq*.) (collectively, "New Jersey No-Fault Law"); Michigan's No-Fault Automobile Insurance Act (Mich. Comp. Laws § 500.3101, *et seq*.) ("Michigan No-Fault Law"); Pennsylvania's Motor Vehicle Financial Responsibility Law (75 Pa. Cons. Stat. § 1701, *et seq*.) and the regulations relating to the same (31 Pa. Code § 69.1, *et seq*.) ("Pennsylvania No-Fault Law"); Florida's Motor Vehicle No-Fault Law (Fla. Stat. § 627.730, *et seq*.) ("Florida No-Fault Law"); and Kentucky's Motor Vehicle Reparations Act (Ky. Rev. Stat. § 304.39, *et seq*.) ("Kentucky No-Fault Law").

82. While the No-Fault laws of these six States have some variation, all agree that an auto insurer is only required to reimburse for treatment that was actually rendered and that was medically necessary (as detailed *infra*).

83. Thus, Ameritox's practice of billing for unnecessary and duplicative urine drug testing (discussed *infra*) renders it ineligible to submit and demand payment under the No-Fault laws of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky.

A. NEW YORK NO-FAULT LAW

84. Under the New York No-Fault Law, automobile insurers are required to provide personal injury protection benefits ("New York No-Fault Benefits") to claimants.

85. New York No-Fault Benefits include up to $50,000 per claimant for reasonable expenses that are incurred for necessary healthcare goods and services.

86. Under the New York No-Fault Law, individuals are entitled to be compensated for "basic economic loss" resulting from injuries caused by the operation of a motor vehicle.

87. "Basic economic loss" is defined to include "all necessary expenses" for medical services. N.Y. Ins. Law § 5102(a)(1); 11 NYCRR § 65-1.1.

88. "[F]or treatment or services to be medically necessary, it must be reasonably determined by the health care professional in consultation with the patient, that the treatment or

services are consistent with the patient's condition, circumstances and best interest of the patient with regard to the type of treatment or services rendered, the amount of treatment or services rendered, and the duration of the treatment or services rendered. To find treatment or services are not medically necessary, it must be reasonably shown by medical evidence, in consideration of the patient's condition, circumstances, and best interest of the patient, that the treatment or services would be ineffective or that the insurer's preferred health care treatment or lack of treatment would lead to an equally good outcome." Fifth Ave. Pain Control Ctr. v. Allstate Ins. Co., 766 N.Y.S.2d 748, 754 (N.Y. Civ. Ct. 2003).

89. "When a claimant, or its assignee, makes a claim, an insurer may deny it on the grounds that the services rendered are not medically necessary." Precision Diagnostic Imaging, P.C. v. Travelers Ins. Co., 795 N.Y.S.2d 875, 878 (N.Y. Civ. Ct. 2005).

90. "To permit medical providers to receive reimbursement even when the insurer has proven that the service provided was not medically necessary would encourage fraud, rather than combat it." Id. at 879.

B. NEW JERSEY NO-FAULT LAW

91. The underlying purpose of New Jersey's No-Fault Law "is to assure that an injured party is promptly compensated for medical treatment resulting from injuries sustained in an automobile accident." Everett v. State Farm Indem. Co., 818 A.2d 319 (2003).

92. New Jersey's No-Fault Law provides for "[p]ayment of medical expense benefits in accordance with a benefit plan provided in the policy and approved by the commissioner, for reasonable, necessary, and appropriate treatment and provision of services to persons sustaining bodily injury, in an amount not to exceed $250,000 per person per accident." N.J. Stat. Ann. 39:6A-4(a).

93. Healthcare providers must show that the services for which they are seeking payment are medically necessary.

94. N.J. Stat. Ann. 39:6A-2(m) states:

> "Medically necessary" means that the treatment is consistent with the symptoms or diagnosis, and treatment of the injury:
>
> (1) is not primarily for the convenience of the injured person or provider,
>
> (2) is the most appropriate standard or level of service which is in accordance with standards of good practice and standard professional treatment protocols, as such protocols may be recognized or designated by the Commissioner of Banking and Insurance, in consultation with the Commissioner of Health and Senior Services or with a professional licensing or certifying board in the Division of Consumer Affairs in the Department of Law and Public Safety, or by a nationally recognized professional organization, and
>
> (3) does not involve unnecessary diagnostic testing.

95. "[A] necessary medical expense under the [New Jersey No-Fault Law] is one incurred for a treatment, procedure, or service ordered by a qualified physician based on the physician's objectively reasonable belief that it will further the patient's diagnosis and treatment. The use of the treatment, procedure, or service must be warranted by the circumstances and its medical value must be verified by credible and reliable evidence." Thermographic Diagnostics v. Allstate Ins. Co., 593 A.2d 768, 780 (1991).

C. MICHIGAN NO-FAULT LAW

96. Michigan's No-Fault Law provides for the payment of unlimited medical and rehabilitative benefits on a first-party payor basis for injured victims of motor vehicle accidents.

97. Personal protection insurance benefits are payable for "[a]llowable expenses consisting of all reasonable charges incurred for reasonably necessary products, services and

accommodations for an injured person's care, recovery, or rehabilitation" arising out of a motor vehicle accident. Mich. Comp. Laws § 500.3107(1)(a).

98. "In order for a no-fault insurer to be responsible for a particular expense, three requirements must be satisfied: (1) the expense must have been incurred by the insured, (2) the expense must have been for a product, service, or accommodation reasonably necessary for the injured person's care, recovery, or rehabilitation, and (3) the amount of the expense must have been reasonable." Hamilton v. AAA Mich., 248 Mich. App. 535, 543 (2001).

99. "Under [the No-Fault] statutory scheme, an insurer is not liable for any medical expense to the extent it is not a reasonable charge for the particular product or service, or if the product or service itself is not reasonably necessary." Nasser v. Auto Club Ins. Ass'n, 457 N.W.2d 637, 645 (1990).

100. A claimant who seeks to hold an insurer liable for No-Fault benefits has the burden of proving that the service claimed is reasonably necessary and that the charge for the service is reasonable. Id.

101. Claims for personal injury benefits under the Michigan No-Fault Law are available only if the benefits are "for accidental bodily injury" and only if those injuries "aris[e] out of" or are caused by "the ownership, operation, maintenance or use of a motor vehicle . . . ." Mich. Comp. Laws § 500.3105(1).

102. The Michigan No-Fault Law provides that an insurer "may be allowed by a court an award of reasonable sum against a claimant as an attorney's fee for the insurer's attorney in defense against a claim that was in some respect fraudulent or so excessive as to have no reasonable foundation." Mich. Comp. Laws § 500.3148(2).

D. FLORIDA NO-FAULT LAW

103. "The purpose of Florida's No-Fault Law is to provide for medical, surgical, funeral, and disability insurance benefits without regard to fault, and to require motor vehicle insurance securing such benefits, for motor vehicles required to be registered in this state and, with respect to motor vehicle accidents, a limitation on the right to claim damages for pain, suffering, mental anguish, and inconvenience." Fla. Stat. § 627.731.

104. An auto insurer is only required to pay "[e]ighty percent of all reasonable expenses for medically necessary medical, surgical, X-ray, dental, and rehabilitative services . . . ." Fla. Stat. § 627.736(1)(a).

105. Pursuant to Fla. Stat. § 627.732(2):

> "[M]edically necessary refers to a medical service or supply that a prudent physician would provide for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or symptom in a manner that is:
>
> (a) In accordance with generally accepted standards of medical practice;
>
> (b) Clinically appropriate in terms of type, frequency, extent, site, and duration; and
>
> (c) Not primarily for the convenience of the patient, physician, or other health care provider."

106. Florida's No-Fault Law does not require Allstate to pay claims based on false or misleading statements relating to the charges.

107. Florida Statute § 627.736(5)(b)(1)(c) provides: "[a]n insurer or insured is not required to pay a claim or charges: . . . [t]o any person who knowingly submits a false or misleading statement relating to the claim or charges."

108. "[T]he plain language of section 627.736(5)(b)(1)(c) . . . relieves both the insurer and the insured from paying the claims of 'any person who knowingly submits a false or misleading statement relating to the claim or charges.' Although 'claim' and 'charges' are not defined by the PIP statutes, and no cases have been suggested to us that define those terms in the context of PIP claims, it is logical to conclude that the Legislature established that dichotomy to be certain that not only the specific individual offensive 'charges' were invalidated, but also that the entire 'claim,' i.e., the collective of all charges, was invalidated, as well." Chiropractic One, Inc. v. State Farm Mut. Auto., 92 So. 3d 871, 874 (Fla. Dist. Ct. App. 5th Dist. 2012).

109. "The revision of the PIP statute had as a goal, among other things, the curtailment of the perceived fraud in the PIP billing of medical services. It is perfectly consistent with that goal for the Legislature to intend to invalidate a billed claim if there is any knowing submission of false or misleading statements relating to the claim or charges submitted by a provider." Id. at 875.

E. PENNSYLVANIA NO-FAULT LAW

110. The Pennsylvania No-Fault Law requires automobile insurance companies to provide insurance coverage "for reasonable and necessary medical treatment and rehabilitative services . . . ." 75 Pa. Cons. Stat. § 1712(1).

111. "The legislature has not defined the terms reasonable and necessary. We must therefore give those terms their common and ordinary meaning. *See* 1 Pa. Cons. Stat. § 1903(a) (directing that words and phrases shall be construed according to rules of grammar and according to their common and approved usage, unless they are defined or have acquired a peculiar and appropriate meaning)." Tagliati v. Nationwide Ins. Co., 720 A.2d 1051, 1056 (Pa. Super. 1998).

112. "[W]e believe that the decision of whether . . . any . . . treatment . . . is reasonable and necessary is one which must be viewed under an objective and reasonable standard." Id.

113. "In other words, an insured must demonstrate that the treatment was warranted by the circumstances . . . . [and] the value of the treatment must be verified by credible and reliable evidence." Id. (internal citations omitted).

114. "If it is determined . . . that a provider has provided unnecessary medical treatment . . . the provider may not collect payment for the medically unnecessary treatment . . . . If the provider has collected such payment, it must return the amount paid plus interest at 12% per year within 30 days." 75 Pa. Cons. Stat. § 1797(b)(7).

F. KENTUCKY NO-FAULT LAW

115. An auto insurer is only required to reimburse for medical expenses, defined as "reasonable charges incurred for reasonably needed products, services, and accommodations, including those for medical care, physical rehabilitation, rehabilitative occupational training, licensed ambulance services, and other remedial treatment care." Ky. Rev. Stat. § 304.39-020(5)(a).

116. Medical expenses must not only be reasonable, but they must be incurred as a result of the accident, and when the evidence is not conclusive, a jury is not required to accept the medical bills submitted by the plaintiff. Thompson v. Piasta, 662 S.W.2d 223 (Ky. App. 1983).

117. The factfinder must weigh the evidence and testimony and decide whether the medical expenses are reasonable and incurred as a result of the accident. Lewis v. Grange Mutual Casualty Co., 11 S.W.3d 591, 593 (Ky. App. 2000).

V. FRAUDULENT PRACTICES TO OBTAIN REFERRALS AND MAXIMIZE REVENUE

118. The defendants had a singular objective: to generate as many claims for payment as possible.

119. To this end, the defendants engaged in a number of unlawful and improper practices designed to increase the number of urine samples referred to Ameritox by treating providers.

120. These practices and actions were undertaken in violation of several federal and state laws.

121. The defendants continue to engage in many fraudulent practices and activities with respect to the claims submitted to Allstate.

A. KICKBACKS

122. Ameritox relies on referrals from treating providers for urine drug testing to sustain its business.

123. As part of their efforts to obtain as many urine drug testing referrals as possible, the defendants provided direct financial inducements and incentives (i.e., kickbacks) to referring providers.

124. For example, the defendants supplied providers with urine specimen cups free of charge or well below market price with the knowledge that the cups would be used by the referring provider to bill Allstate for in-office testing of patient urine samples, or what is commonly referred to as point-of-care testing.

125. The provision of point-of-care testing cups for free or below market value constitutes an unfair financial inducement when the referring provider uses that cup to test, bill for, and receive additional revenue from payors like Allstate.

126. In exchange for free or discounted point-of-care testing cups, the treating provider agreed to refer patient urine samples to Ameritox for additional testing.

127. The defendants instructed Ameritox employees to supply medical providers with free or discounted specimen cups in exchange for the referral to Ameritox.

128. By taking and using the free cups from Ameritox, referring providers paid less for their in-office testing than if they had purchased the cups at fair market value.

129. Ameritox's fraudulent scheme to obtain referrals through the provision of point-of-care testing cups for free or below market value is almost indistinguishable from the conduct engaged in by one of Ameritox's largest competitors in the urine drug testing market, conduct that required Millennium Health, LLC f/k/a Millennium Laboratories, Inc. ("Millennium") to pay the United States $227 million dollars to resolve the government's claims regarding "[urine drug testing] referred by physicians who received free point-of-care drug testing supplies in violation of the Stark Law . . . and the Anti-Kickback Statute . . . ." *See* Exhibit 7.

130. Additionally, the defendants engaged in and encouraged the practice of supplying gift cards to treating providers to encourage referrals.

131. Ameritox also made direct cash payments to treating providers based on the number of referrals sent to Ameritox.

132. For example, at one time, Ameritox paid referring providers $10 for each urine specimen referred to Ameritox.

133. Ameritox is aware that the practice of providing healthcare providers with free or below fair market value items and services to influence and induce referrals of lab specimens is unlawful.

134. In or before 2010, Ameritox was the focus of a Department of Justice ("DOJ") investigation which found that from January 2, 2003, through December 31, 2006, Ameritox offered and/or paid cash remuneration to healthcare providers who referred drug testing business to Ameritox, which remuneration was intended to induce such referrals, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Prohibition Against Certain Physician Self-Referrals, 42 U.S.C. § 1395nn ("Stark Law").

135. The DOJ investigation also found that from January 1, 2003, through June 30, 2010, Ameritox offered and/or provided, directly or through a third party, to healthcare providers who referred drug testing business to Ameritox, remuneration in the form of the services of specimen collectors and/or processors placed in providers' offices, which remuneration was intended by Ameritox to induce such referrals in violation of the Anti-Kickback Statute and Stark Law.

136. These illegal and fraudulent activities were brought to light when a former Ameritox employee filed a lawsuit against Ameritox under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729, *et seq*. United States *ex rel.* Maul v. Ameritox, LLC., 8:07-cv-00953-RAL-EAJ, United States District Court for the Middle District of Florida.

137. Ameritox and the DOJ reached an agreement to settle that case pursuant to which Ameritox paid a $16.3 million civil settlement.

138. In its press release announcing the settlement, the DOJ stated that "[t]he settlement resolves allegations that Ameritox made cash payments to its physician clients from January 1, 2003 through December 31, 2006 to induce the referral of drug testing services. It also resolves claims arising from the offer by Ameritox of free collector personnel to its physician clientele from January 1, 2003 through June 30, 2010, in order to induce the referral of Medicare business." *See* Exhibit 8.

139. In addition to agreeing to pay $16.3 million, Ameritox also entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General for the Department of Health and Human Services that requires an independent company to scrutinize Ameritox's contractual relationships. *See* Exhibit 9.

140. The CIA entered into by Ameritox establishes procedures it is required to implement to become compliant with federal healthcare laws, in particular the Anti-Kickback Statute and Stark Law. Id.

141. Ameritox must also engage an Independent Review Organization to oversee its compliance with the provisions set forth in the CIA. Id.

142. The CIA dictated that Ameritox adhere to an enforced period of compliance obligations for five years from October 22, 2010, the effective date of the CIA. Id.

B. PRESSURE ON SALES REPRESENTATIVES TO INCREASE THE NUMBER OF REFERRALS

143. In addition to the use of kickbacks to referring providers, the defendants also strongly pressured sales representatives to increase the number of test referrals from treating providers to Ameritox.

144. This pressure took a number of forms, including (1) instructing sales representatives to demand that the referring provider choose specific panels of urine drug testing, (2) instructing sales representatives to target certain payor sources, and (3) tying sales representatives' commissions to the number of test referrals they procured.

145. These tactics did not take into consideration the medical necessity of the urine drug testing, but rather were done solely to benefit the defendants.

1. Preselected Testing Panels

146. Ameritox management, including Backer, Leider, Walton, Lopes, and Zimmerman, through the development and use of the recurring order form, did not allow referring providers to choose only one or a few drugs/drug classes to be tested by Ameritox, but rather required that the referring provider choose a full testing panel that consists of at least eight (8) drug classes to be tested on every single specimen referred by that provider.

147. Thus, Ameritox ensured that it would be able to bill for at least eight (8) tests, without regard to patient-specific need, for every single urine specimen it is referred.

148. These preselected testing panels were improper for a number of reasons, including that they were not patient-specific and lead to unnecessary and excessive testing (discussed in detail *infra*).

149. In fact, in addition to Millennium agreeing to resolve the government's claims that Millennium distributed free POCT cups in exchange for referrals in violation of the Stark Law and Anti-Kickback, Millennium's $227 million dollar settlement also resolved the government's claims regarding "excessive and unnecessary UDT [urine drug testing] ordered by physicians without an individualized assessment of patient need[.]" *See* Exhibit 7.

150. Ameritox management, including Backer, Leider, Walton, Lopes, and Zimmerman, encouraged sales representatives to push the most extensive panel preference on treating providers to ensure the highest number of tests performed on each specimen referred to Ameritox.

151. Indeed, Ameritox's management engaged in conduct that was substantially similar to the conduct of Millennium's management, conduct that led to Millennium's settlement agreement with the United States wherein Millennium expressly agreed that the "Covered Conduct" being resolved by the settlement included "excessive and unnecessary UDT [urine drug

testing] ordered by physicians without an individualized assessment of patient need (as described in paragraphs 85-145 and 176-266 of the United States' Complaint." Id.

152. The "Covered Conduct" for which Millennium agreed to pay the government almost quarter of a billion dollars includes extensive discussion of Custom Profiles (i.e., standing orders, which Ameritox calls "recurring order" forms) and non-patient-specific ordering that echo Allstate's allegations against Ameritox made herein, including:

a. "A core element of Millennium's business model was the use of physician standing order forms. Millennium created the forms as part of its plan to direct physicians to establish protocols for laboratory testing to be performed on all of their patients – usually, at a minimum, a dozen or more drug tests – regardless of each patient's individualized need and condition." *See* Exhibit 10, ¶ 88.

b. "Millennium expected not only that physicians would have a Standing Order or Custom Profile, but also required certain testing thresholds, so that Millennium could make more money. Millennium refused to do business with accounts that failed to meet these thresholds." Id. at ¶ 95.

c. "Millennium employees routinely submitted completed Custom Profile forms to headquarters for processing . . . and often filled out information on the Custom Profile forms themselves." Id. at ¶ 98 (internal citation omitted).

d. "Millennium even processed specimens under customers' Custom Profiles in instances where the 'Use Custom Profile' box in Section A of the requisition form was left blank." Id. at ¶ 99.

e. "Millennium required that physicians agree to Custom Profiles with at least twelve tests in several contexts, including approval as a Millennium customer, removal from 'troubled' (unprofitable) account lists, and as a condition for receiving free POC test cups." Id. at ¶ 101.

f. "Millennium trained its sales representatives to emphasize to physicians that they should not individually assess their patients, but rather extensively test all patients – with separate, expensive laboratory tests – pursuant to pre-determined Custom Profiles. . . ." Id. at ¶ 117.

g. "Millennium emphasized profits above compliance and intimidated sales representatives to engage in marketing tactics designed to generate UDT orders that were not patient-specific and not reasonable and necessary for patient diagnosis or treatment. . . ." Id. at ¶ 192.

153. The defendants, by and through the sales representatives, also encouraged their physician-clients to test more frequently and for additional drugs beyond the preselected panel.

154. By cultivating an environment where pushing the most extensive testing panel on clients was demanded of sales representatives, Ameritox and its management, including Backer, Leider, Walton, Lopes, and Zimmerman, substantially inflated drug testing revenues through the use of preselected panel preferences that resulted in unnecessary testing.

2. Targeted Payors

155. The defendants were aware that certain payor sources are more likely to pay Ameritox's bills than others.

156. As such, Ameritox management, including Walton, Lopes, and Zimmerman, advised employees to identify the insurer/payor source of the treating provider's patients and to

pressure the treating provider to refer for testing the urine samples of those patients covered by a favorable payor source.

157. This process allowed the defendants to focus urine drug testing on patients who were covered by insurance or another payor program that historically paid for Ameritox's testing procedures, including auto insurers like Allstate.

158. Ameritox management, including Walton, Lopes, and Zimmerman, trained their sales representatives to identify and test patients more frequently based on whether or not the patient's insurance company typically reimbursed Ameritox for its testing.

159. To help ensure that Ameritox only tested specimens from patients who were covered by an acceptable payor program, Ameritox management, including Walton, Lopes, and Zimmerman, established a policy of not compensating sales representatives for testing that was performed on specimens that were billed to non-paying insurers/sources.

160. For example, Ameritox sales representatives, at the direction of Walton, Lopes, and Zimmerman, discouraged their clients from doing any testing of Medicaid patients since Medicaid historically did not reimburse/allow Ameritox to bill for such services.

161. The defendants also established a policy of not compensating sales representatives for Medicaid urine samples sent in for testing.

162. This further incentivized the sales representatives to pressure referring providers to focus on increasing the number of referrals from paying sources, such as Allstate and Medicare.

163. Not only did the defendants pressure sales representatives to target patients with certain insurance, the defendants also docked sales representatives' commissions for samples that were tested but not reimbursed.

164. Thus, the defendants engaged in a calculated scheme to determine what payor agencies and payor insurance carriers were most likely to reimburse for the urine drug testing billed by Ameritox.

165. This scheme bore no relation to the clinical and medical needs of patients, but rather was devised and implemented for the sole purpose of generating revenue for the defendants.

166. The provision of unnecessary and excessive testing based on the payor source instead of medical necessity is unlawful and invalidates every claim for payment submitted to Allstate by Ameritox.

3. Commission-Driven Testing Protocols

167. Compensation for Ameritox's sales representatives was based on the number of tests performed on each urine specimen submitted by the representatives' provider-clients.

168. As such, sales representatives pressured referring providers to choose the most expensive predetermined testing panel rather than allowing providers to submit testing requests based on each patient's clinical need.

169. Ameritox management, including Walton, Lopes, and Zimmerman, also trained their employees to encourage providers to gather urine specimens from patients during each visit in order to generate the most revenue for Ameritox.

170. Ameritox's management, including Walton, Lopes, and Zimmerman, cultivated an environment of revenue-based sales incentives over medical necessity when developing its clientele and training sales representatives.

171. Ameritox management, including Walton, Lopes, and Zimmerman, developed a training program that encouraged sales representatives to focus on generating the most profit from

a single urine specimen for the sole purpose of generating income via medically unnecessary and excessive testing.

172. Because sales representatives' compensation was based on the number of samples collected and submitted for testing each month, it was incumbent on the sales representative (and stressed repeatedly by Ameritox management) to increase the number of urine samples submitted for testing by each sales representative's individual doctor/clinic clients.

173. Thus, the single-minded culture established at Ameritox to obtain as many referrals as possible extended to all employees, including the sales representatives whose livelihood depended on the number of tests they convinced treating providers to request from Ameritox.

174. This culture necessarily did not take into account the necessity of such urine drug tests, but rather ignored that factor in favor of increased revenues.

C. UNLAWFUL USE OF IN-OFFICE SPECIMEN PROCESSORS

175. In furtherance of its goal to obtain as many referrals as possible, the defendants employed a practice whereby they placed Ameritox-paid employees known as specimen processors in the offices of referring providers at no cost to the referring provider if he or she agreed to submit a minimum number of urine samples to Ameritox.

176. The job of the specimen processor was to collect urine samples from the treating provider's patients.

177. The single patient urine sample was then usually tested by both the treating provider (i.e., point-of-care testing billed separately to payors such as Allstate) and by Ameritox.

178. The specimen processor also completed paperwork to expedite shipment of the urine samples to Ameritox.

179. Ameritox used this practice to provide illegal kickbacks to healthcare providers by providing them with free on-site specimen processors.

180. Under the guise of an arrangement with a purported "third-party" vendor that employed specimen processors but that also had close ties to Ameritox, the defendants oversaw the critical aspects of each specimen processor's employment such that the processor effectively became an Ameritox employee.

181. The defendants interviewed candidates for specimen processor positions, made hiring decisions, and paid their salaries.

182. Additionally, Ameritox sales representatives – and not the third-party vendor – supervised the specimen processors and determined where to place them among Ameritox's customers.

183. The defendants also closely correlated the processors' working hours to the number of referrals they improperly could induce out of the placement.

184. That is, as a condition for a treating provider to have a specimen processor placed in his or her office at no cost, the treating provider was required to promise that he or she would refer a certain quota of urine samples to Ameritox for each hour that the specimen processor was at the treating provider's clinic.

185. The duties of Zimmerman, Ameritox's Chief Laboratory Officer, included supervising Ameritox's Specimen Processor Program, which included the training requirements for specimen processors who were employed by third-party vendor All Medical Personnel, Inc., but were placed by and performed work for the benefit of Ameritox.

186. In Florida, Ameritox's longstanding practice of using specimen processors was specifically disallowed as unlawful. *See* Fla. Stat. § 483.245.

187. Florida's Agency for Health Care Administration ("AHCA") promulgated a rule that expressly prohibited laboratories in Florida from providing "personnel or assistance of any kind to perform any duties for the collection or processing of specimens" because such provision of free services is a kickback to the referring physician. *See* Fla. Admin. Code R. 59A-7.020(14)(g); *see also* In re: Petition for Declaratory Statement of Dominion Diagnostics, LLC, AHCA Final Order at 5-6 (July 8, 2008).

188. On January 18, 2011, the Florida AHCA demanded that Ameritox immediately cease its practice of placing specimen processors in physician offices "or face the prospect of administrative fines under the Florida anti-kickback laws." *See* Exhibit 11.

189. In response to a letter sent by Ameritox, on March 16, 2011, the Florida AHCA reiterated its position and again directed Ameritox to "stop sending specimen processors/collectors to doctor's offices immediately" because such practices "are a violation of section 59A-7.020(14)(g)" of the Florida Administrative Code. *See* Exhibit 12.

190. The letter continues, "[f]ailure to immediately cease this activity will result in an administrative fine under section 483.221, Florida Statute of $1,000 per violation, other action as outlined in section 483.23, Florida Statutes or both." Id.

191. New Jersey also adopted a similar ban on the use of specimen processors.

192. The change in New Jersey law was in response to an apparent increase of reports "that rental agreements between laboratories and physicians for physician office collection stations [in the physicians' offices] exceed fair market value and influence the selection of laboratory services." 42 N.J.R. 1530(a), pg. 1532.

193. The New Jersey Department of Health and Senior Services prohibited lease agreements and service agreements between clinical laboratories and physicians via a ban effective on or about July 19, 2010. Id.

194. The defendants' widespread use of specimen processors to guarantee referrals to Ameritox is in violation of several laws and is further indicative of the extent of measures taken by the defendants to obtain referrals at any cost.

D. FALSE ADVERTISING

195. Ameritox has a history of publishing false statements to the public for the purpose of misleading potential clients regarding the accuracy and capability of its urine drug testing services, including false advertisements published during the time frame at issue in this Complaint.

196. Several of Ameritox's advertisements were determined by a jury to have contained a literally false message. *See* Exhibit 13.

197. Ameritox entered into a Consent Order after it was determined that the advertisements in question contained false messages. *See* Exhibit 14.

198. The Consent Order provides:

> Within thirty days of the entry of this Order, Ameritox, through its CEO, will send a letter on Ameritox letterhead (12 pt. font, not to exceed two pages) to all Ameritox's current customers explaining the events described in this Order, including but not limited to the following points, which shall appear on the first page:
>
> - That the Court, having concurred with a jury's advisory verdict, concluded that three Ameritox Rx Guardian advertisements that ran in 2008 and 2009 contained literally false statements. The false statements included language stating that Rx Guardian can 'determine dosage compliance,' 'verify dosage compliance,' and other phrases that convey such meaning.
>
> - No urine drug test can definitively determine whether a patient has taken the dosage of medication prescribed.

- The Court also concluded that a June 9, 2011 Rx Guardian CD Fact Sheet constitutes a false advertisement. In the Fact Sheet, Ameritox referred to patients in its Rx Guardian CD reference database as "known" adherent patients, which the Court found to be a false statement because the patients were 'clinically assessed' to be adherent by the Marshfield Clinic, but were not 'known' to be adherent.

- Ameritox has maintained that its Rx Guardian and Rx Guardian CD services constitute merely one tool to assist physicians in making their own independent determinations regarding patient adherence to prescription regimes and that physicians should always use their clinical judgment in combination with all available information in making those determinations.

Before sending to customers the Ameritox letter referenced above, Ameritox will submit a draft of the letter to Judge Gallagher for her review to ensure that the letter as a whole includes the enumerated items and fairly presents the outcome of the dispute.

Id.

199. Ameritox has been found to have disseminated false and misleading communications to the public regarding its testing services.

200. Ameritox's false advertising, like the myriad of other illicit practices discussed herein, was aimed at increasing Ameritox's revenue to the exclusion of all other considerations, including the lawfulness and necessity of its testing services.

201. Ameritox used its false advertising to attract physicians to refer for urine drug testing that could not provide the results promised by Ameritox.

VI. FRAUDULENT UNNECESSARY, UNREASONABLE, EXCESSIVE, AND DUPLICATIVE TESTING

202. At all times relevant to this Complaint, the defendants had a singular objective: to generate as many claims for payment as possible and to use each claim to individually charge for urine drug testing that was performed, if at all, in violation of the established standards of care for urine drug testing.

203. The defendants' efforts to bill for as much unnecessary testing as possible is confirmed by several former Ameritox sales representatives.

204. The defendants' efforts to bill for as much unnecessary testing as possible is also confirmed by the limited panel preference options (each of which requires that a high minimum number of drugs/drug classes be tested on every specimen), recurring order, and other forms that the defendants mandated be used with respect to every referring provider, as detailed below.

205. Ameritox management, including Walton, Lopes, and Zimmerman, instructed and encouraged sales representatives to promote unnecessary testing in order to maximize Ameritox's profits.

206. The unnecessary, unreasonable, excessive, and duplicative urine drug testing performed and encouraged by the defendants included (1) unnecessary confirmatory testing of negative screening results, (2) unnecessary quantitative confirmation testing, (3) duplicative screening testing, and (4) performing tests that were not ordered by the treating provider.

A. QUALITATIVE VS. QUANTITATIVE URINE DRUG TESTING

207. Non-emergency testing of urine for drugs of abuse is performed to determine compliance with drug rehabilitation programs; to detect drug abuse in asymptomatic patients; or, as relevant to the patients at issue in this Complaint, to determine compliance with pain management treatment.

208. Clinical urine drug testing can be a one-step process using an initial test ("screen") comparing the result to a cutoff value, which defines the result as a "positive" or "negative" screening result.

209. Alternatively, clinical urine drug testing can be a two-step process of initial test, as described above, and the confirmation of the initial test "positive" results by a second test which uses a different method and which is more sensitive and more specific than the screening test.

210. Clinical laboratories like Ameritox use urine drug testing methods that are classified as qualitative or quantitative.

211. The American Medical Association ("AMA") defines "qualitative" tests as those "that detect whether a particular analyte, constituent, or condition is present." *CPT Assistant, Fall 1993*.

212. The AMA defines "quantitative" tests as those "that give results expressing the specific numerical amount of an analyte in a specimen." Id.

213. The AMA further states that quantitative testing (as defined above) "is in contrast to qualitative tests." Id.

214. A qualitative drug test indicates whether a particular drug and/or its metabolites[1] is likely to be present in a specimen, but not the specific concentration of the drug.

215. The result of a qualitative test is reported as "positive" or "negative" (i.e., presumptively present or presumptively not present).

216. A qualitative urine test is sometimes referred to as a "urine screen" because qualitative testing is used to screen whether a drug is present or not in the patient's system.

217. The purpose of performing qualitative urine drug screens is to determine quickly and reasonably accurately whether any one of several drugs and/or drug classes is likely to be present in the specimen.

[1] A metabolite results when a drug is broken down by the body into a modified form of the drug. The use of the word "drug" throughout this Complaint includes any metabolites of the drug, unless specifically stated otherwise.

218. In contrast to qualitative urine drug testing, quantitative testing produces a discrete numeric value representing the concentration of the drug in the sample using a more complex and expensive testing method than qualitative testing.

B. BILLING FOR URINE DRUG TESTING

219. The defendants submitted reimbursement claims to Allstate through the U.S. Mail on Health Insurance Claim Forms ("HICF") (also known as "CMS-1500" claim forms) approved by the National Uniform Claim Committee ("NUCC") and referenced in the NUCC Instruction Manual.

220. The back of all HICF forms contains the following language in bold font: "NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

221. The defendants submitted reimbursement claims to Allstate containing Current Procedural Terminology ("CPT") Codes and Healthcare Common Procedure Coding System ("HCPCS") Codes seeking payment for drug testing purportedly performed on urine specimens received from referring providers located in New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky, as well as numerous other States not at issue in this Complaint.

222. CPT Codes are published annually by the AMA to facilitate the efficient processing of healthcare charges by insurance carriers and other private and governmental healthcare payors.

223. HCPCS Codes were developed to ensure claims processed by Medicare and other insurance programs are done so in an orderly and consistent manner.

224. According to the Health Insurance Portability and Accountability Act ("HIPAA"), all healthcare providers are mandated to bill insurance carriers, including auto insurance carriers

like Allstate, utilizing the HIPAA-defined standard transaction code sets (which, in the context of this Complaint, are the CPT and HCPCS Codes).

225. Each provider has the responsibility to select the CPT and/or HCPCS Code that accurately and truthfully identifies the services performed and the complexity involved in rendering those services.

226. The CPT Code Book and HCPCS Code Book each detail which urine drug testing billing codes are applicable when submitting a reimbursement claim seeking payment for a qualitative urine drug screen.

227. The CPT Code Book also details the correct CPT Codes for the more specific and complex quantitative urine drug tests.

228. Codes in the Pathology and Laboratory chapter of the CPT manual that can be used for urine drug testing are defined as qualitative or quantitative.[2]

229. CPT Codes for quantitative testing are typically specific to the type of drug being measured in a specimen or the quantitative testing methodology.

230. For example, quantitative testing for amphetamines is reported using CPT Code 82145 (Amphetamine or methamphetamine).

231. Quantitative testing for phencyclidine (PCP) is reported using CPT Code 83922.

232. Quantitative testing for barbiturates is reported as CPT Code 80184 (Phenobarbital) or CPT Code 82205 (Barbiturates, not elsewhere specified).

[2] As of January 1, 2015, the AMA made several changes to the Pathology and Laboratory 80000 series code section of the CPT Code Book. Specifically, the 2015 revised codes allow for additional specificity in differentiating the type of specimen being tested. The drug procedures are now divided into the following subsections: 1) Drug Assay; 2) Therapeutic Drug Assays; and 3) Chemistry. Under Drug Assay, presumptive procedures are used to identify possible use or non-use of a drug or drug class and may be followed by a definitive test to specifically identify drugs or metabolites. Definitive drug testing may be quantitative or qualitative and does not require prior presumptive testing. Therapeutic Drug Assays are performed to monitor clinical response to a known, prescribed medication. The overwhelming majority of claims at issue in this Complaint relate to dates of service before January 1, 2015. As such, the allegations of this Complaint use the previous AMA billing and coding rules unless stated to the contrary.

233. Quantitative urine drug testing is billed for each and every drug/drug category tested.

234. In contrast, several CPT and HCPCS Codes for qualitative urine drug testing only permit the submission of a single billing code for the entire screening test performed regardless of the number of specific drugs/drug categories tested.

235. Medicare, for example, which uses HCPCS Codes, does not allow clinical laboratories to bill more than one qualitative urine drug testing billing code per patient per encounter.

236. Thus, quantitative testing is almost always more expensive than qualitative testing and results in higher reimbursement to the laboratory (Ameritox) because (1) qualitative codes are ordinarily bundled and only one code is billed regardless of the number of drugs tested while quantitative codes are billed for each drug tested and (2) quantitative tests are more complex and expensive to perform and, therefore, have higher reimbursement.

237. The onus is on the laboratory to select the appropriate billing code based on the type of urine drug test performed (i.e., qualitative or quantitative).

C. UNNECESSARY CONFIRMATORY TESTING OF NEGATIVE SCREENING RESULTS

238. Ameritox routinely performed qualitative urine drug testing that was almost always performed by an immunoassay testing method (designated by the inclusion of "(IA)" on Ameritox's lab reports next to each drug/drug class tested). *See, e.g.*, Exhibit 15.

239. Ameritox confirms on its lab reports that immunoassay testing is done to screen for the presence of a substance: "Immunoassay (IA) screening establishes the presence of a drug or compound in a significant quantity to require confirmatory testing. When a negative IA result is reported, the amount detected, if any, is below the established cutoff level . . . ." Id.

240. Ameritox billed Allstate for this qualitative/screening urine drug testing using CPT Code 80101 ("[d]rug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class").

241. For dates of service after January 1, 2010, Ameritox also billed for its qualitative/screening urine drug testing using HCPCS G0431 ("[d]rug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class").[3]

242. For every claim at issue in this Complaint, Ameritox also billed Allstate for quantitative testing that was purportedly done.

243. Such quantitative testing was unnecessary and violative of the standard of care for clinical laboratories for at least one of two reasons.

244. First, to the extent Ameritox performed both qualitative and quantitative urine drug testing on the same specimen by the same testing methodology (e.g., immunoassay testing), Ameritox improperly performed (and fraudulently billed for) duplicate testing.

245. It is not necessary to test a single urine sample more than once using the same testing methodology and, in fact, such a practice is abusive.

246. Ameritox's lab reports do not indicate that a different testing methodology was utilized when a specimen was tested the second time (i.e., when the quantitative test result was reported).

247. Instead, Ameritox's lab report states only once next to each drug/drug category the testing method utilized (e.g., immunoassay ("IA") or mass spectrometry ("MS"). *See, e.g.*, Exhibit 15.

[3] Effective January 1, 2011, the AMA revised HCPCS G0431 to be billed for "[d]rug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter."

248. Billing for the same testing methodology performed more than once on the same specimen is an abusive practice.

249. Second, assuming *arguendo* that Ameritox did utilize a different testing methodology when it performed quantitative testing on specimens that had already been qualitatively tested and yielded a "negative" result, Ameritox unnecessarily confirmed negative qualitative/screening testing results.

250. As discussed above, screening urine drug testing checks for the presence or absence of a drug in a urine sample rather than the precise concentration of the drug.

251. Absent extenuating circumstances (as found and documented by the referring provider), confirmatory testing by any methodology is not necessary where the screening test indicates that a drug is not present in the patient's urine (i.e., the test is negative).

252. Ameritox, however, routinely submitted reimbursement claims to Allstate seeking payment for unnecessary quantitative confirmatory testing it purportedly performed on specimens that yielded negative qualitative/screening results.

253. In rare instances dependent on the individual patient's clinical situation, confirmatory drug testing can be medically necessary when the results of the qualitative/screening test are unexpectedly presumptively positive or when the results of the qualitative test are negative and the negative finding is inconsistent with the patient's medical history.

254. However, for confirmatory testing on a negative qualitative test to be appropriate, the referring provider, and not the testing laboratory, must determine if confirmatory testing is necessary after taking into consideration all known facts at the time the sample is collected.

255. No provider can make a blanket determination across all patients and all dates of service as to what constitutes reasonable confirmatory urine drug testing in all cases.

256. Instead, the individual provider must determine the reasonableness and necessity of urine drug testing on a patient-by-patient and visit-by-visit basis.

257. According to Ameritox's website, there is no need to retest urine samples that generate negative screening results: "Retesting samples screened initially by a laboratory as negative enables companies to charge additional fees for unneeded services — the process neither advances patient care nor controls taxpayer costs. Ameritox, unlike a San Diego company, does not recommend customers retest negative drug samples much less make it a standing practice to retest all negative drug samples." *See* Exhibit 16.

258. Allstate agrees with Ameritox's statement that retesting samples screened initially as negative enables companies, such as Ameritox, to charge additional fees for unnecessary confirmation testing while also failing to advance patient care.

259. Despite its own statement, however, Ameritox consistently submitted reimbursement claims to Allstate seeking payment for quantitative confirmatory testing performed to verify negative qualitative/screening results where both the qualitative and quantitative testing was performed by Ameritox at one of its laboratories.

260. When Ameritox first receives a urine specimen from a referring provider, it performs a qualitative/screening test, as evidenced by the inclusion of qualitative results on its lab reports. *See, e.g.*, the representative lab report annexed hereto at Exhibit 15 in which Ameritox lists the results of all of its qualitative testing in the column labeled "Lab Result (Qualitative)."

261. Ameritox describes its screening test as follows: "An initial Enzyme Immunoassay (EIA) test screens for the presence of opiates, benzodiazepines, illicits and other prescribed or non-prescribed medications in a specimen. The EIA uses antigen antibody reactions to provide fast, reliable results." *See* Exhibit 17.

262. Ameritox's use of the phrase "presence of" indicates its intent that its screening tests are qualitative in nature.

263. Ameritox continues: "If positive, immunoassay is followed by confirmation testing through one of the following methods: (1) Gas chromatography-mass spectrometry is used to create a fingerprint-like match for each detected prescription medication or illicit; or (2) Liquid chromatography-tandem mass spectrometry is used when optimal specificity and sensitivity are required to detect the absence or presence of your patients' prescribed medications as well as the presence of non-prescribed medications or illicits." Id.

264. According to Ameritox's own statements, only a positive screening result should be submitted for confirmation testing.

265. The standard of care for clinical laboratory urine drug testing concurs that only unexpected initial screening results should be confirmed (absent extenuating circumstances that must be documented in the patient's medical records by the treating provider).

266. In clinical urine drug testing, confirmatory testing is not always done and certainly should not be done automatically.

267. Instead, confirmatory testing is to be ordered at the treating physician's discretion, e.g., when an initial screening test result is clinically unexpected (such as when a prescribed drug is reported as negative or when a non-prescribed or illicit drug is reported as positive).

268. Despite its representation to the contrary, Ameritox routinely retested its own negative qualitative/screening urine drug testing results generated by its own screening testing method, a method which Ameritox claims "provide[s] fast, reliable results." Id. (emphasis added).

269. In other words, Ameritox used excessive and unjustifiable quantitative confirmatory testing to confirm the absence of a drug that was clearly reported as "negative," or not present, in the "reliable" screening test performed by Ameritox.

270. The automatic performance of confirmation testing on a test result initially determined "negative" by a screening testing method is incompatible with established standards of care for clinical laboratories, which do not deem confirmatory testing necessary for negative screening results in the absence of a patient-specific order from the treating physician to confirm what appears to be an unexpected negative finding or an unexpected positive finding.

271. For example, the level of confirmation Ameritox performs on the specimens of patients undergoing pain management treatment after involvement in predominately low-level motor vehicle accidents significantly exceeds the level of confirmation required by the Nuclear Regulatory Commission's policy on drug testing confirmation.

272. Persons authorized to operate a nuclear power reactor under the scope of the Nuclear Regulatory Commission (NRC) are required to submit to drug and alcohol testing as part of their continued duties. 10 C.F.R. § 26.31 (NRC's Fitness for Duty Program).

273. The NRC mandates that "[s]pecimens that yield positive initial drug test results or are determined by initial validity testing to be of questionable validity must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested." 10 C.F.R. § 26.31(d)(3).

274. The NRC defines "initial drug test" as "a test to differentiate 'negative' specimens from those that require confirmatory testing." 10 C.F.R. § 26.5.

275. Thus, the NRC does not require that confirmatory testing be performed on negative screening (i.e., initial drug test) results for persons entrusted with operating nuclear reactors.

276. In comparison, Ameritox billed Allstate for unnecessary confirmatory quantitative testing of negative qualitative/screening results for every claim at issue herein, all of which involve patients purportedly injured in low-level motor vehicle accidents and none of whom are known to maintain and/or operate nuclear power reactors or perform other safety-sensitive tasks.

277. The lack of necessity of the quantitative confirmation testing is compounded by the fact that this practice was often done without any evidence that the treating provider specifically requested that the confirmatory quantitative testing be performed.

278. For almost every claim at issue in this Complaint, Ameritox submitted lab reports and bills to Allstate for both qualitative testing (represented by CPT Code 80101 or HCPCS G0431) and quantitative testing (represented by drug-specific CPT Codes).

279. The qualitative urine drug testing results reported by Ameritox were overwhelmingly negative.

280. As such, and as there was not a patient-specific reason documented by a treating physician to perform confirmatory testing, there was no need for Ameritox to perform confirmation testing.

281. In almost every instance where Ameritox reported a quantitative result, Ameritox performed unnecessary quantitative confirmatory testing on negative qualitative/screening test results.

282. Ameritox engaged in a fraudulent scheme designed to obtain payment for excessive and unnecessary quantitative testing to confirm negative qualitative drug test results.

283. This scheme is objectively fraudulent as it disregards established standards of care for when confirmatory testing is necessary.

284. This scheme is also fraudulent according to Ameritox's own statements, as quoted *supra*.

1. Exemplar Claims

285. The existence of a widespread scheme to defraud by billing for unnecessary quantitative confirmation of negative qualitative results is evident across almost all of the claims submitted to Allstate by the defendants, including the specific Allstate insureds/patients discussed herein.

a. C.O. (Claim No. 21109840H8)

286. Patient C.O. purportedly gave a urine sample on February 14, 2012 in the State of Michigan that was tested by Ameritox.

287. Ameritox submitted a report detailing the lab results of C.O.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 18.

288. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

289. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

290. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider and which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

291. According to C.O.'s lab report, qualitative testing for the following ten (10) drug categories yielded a "negative" result: cocaine (benzoylecgonine), marijuana (THCA), phencyclidine, oxycodone/oxymorphone, propoxyphene, benzodiazepines, barbiturates, amphetamines, methadone, and the methadone metabolite EDDP. Id.

292. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

293. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following eight (8) charges: 80154 (benzodiazepines); 82145 (amphetamines or methamphetamine); 82205 (barbiturates); 82520 (cocaine or its metabolite); two units of 83840 (methadone); one unit of 83925 (for the opiate, oxycodone/oxymorphone); and 83992 (phencyclidine). *See* Exhibit 19.

294. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

295. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

296. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in C.O.'s specimen).

297. According to the lab report, the eight (8) above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 18.

298. Allstate was billed $431.20 relative to these eight (8) quantitative testing CPT Codes that were unnecessarily performed to confirm negative qualitative test results. *See* Exhibit 19.

299. Ameritox submitted claims for payment and accompanying medical records relative to C.O. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

300. Allstate relied upon Ameritox's submissions in adjusting the claims.

b. K.P. (Claim No. 2553760691)

301. Patient K.P. purportedly gave a urine sample on April 8, 2013 in the State of Michigan that was tested by Ameritox.

302. Ameritox submitted a report detailing the lab results of K.P.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 20.

303. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

304. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

305. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider and which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

306. According to K.P.'s lab report, qualitative testing for the following ten (10) drug categories yielded a "negative" result: cocaine (benzoylecgonine), marijuana (THCA), MDMA, phencyclidine, oxycodone/oxymorphone, heroin, fentanyl, barbiturates, carisprodol, and amphetamines. Id.

307. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

308. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following five (5) charges: two units of 82145 (amphetamines or methamphetamine); 82205 (barbiturates); 82520 (cocaine or its metabolite); and 83992 (phencyclidine). *See* Exhibit 21.

309. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

310. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

311. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in K.P.'s specimen).

312. According to the lab report, the five (5) above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 20.

313. Allstate was billed $240.96 relative to these five (5) units of quantitative testing that were unnecessarily performed to confirm negative qualitative test results. *See* Exhibit 21.

314. Ameritox submitted claims for payment and accompanying medical records relative to K.P. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

315. Allstate relied upon Ameritox's submissions in adjusting the claims and tendering payment.

c. J.M. (Claim No. 0210378337)

316. Patient J.M. purportedly gave a urine sample on March 5, 2013 in the Commonwealth of Pennsylvania that was tested by Ameritox.

317. Ameritox submitted a report detailing the lab results of J.M.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 22.

318. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

319. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

320. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

321. According to J.M.'s lab report, qualitative testing for the following sixteen (16) drug/drug categories yielded a "negative" result: cocaine (benzoylecgonine), marijuana (THCA), MDMA, phencyclidine, buprenorphine, fentanyl, methadone, its metabolite EDDP, meperidine, tramadol, tapentadol, benzodiazepines, barbiturates, gabapentin, pregabalin, and amphetamines. Id.

322. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

323. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following charges: 80154 (benzodiazepines); two units of 82145 (amphetamines or methamphetamine); 82205 (barbiturates); three units of 82542 (column chromatography/mass spectrometry, analyte not elsewhere specified; quantitative, single stationary and mobile phase) which appears to be associated with testing for marijuana (THCA), gabapentin, and pregabalin; 82520 (cocaine or its metabolite); two units of 83840 (methadone); five units of 83925 (opiate(s), drug and metabolites, each procedure), which appears to be applicable to tramadol, buprenorphine, fentanyl, meperidine and tapentadol; and 83992 (phencyclidine). *See* Exhibit 23.

324. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

325. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

326. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in J.M.'s specimen).

327. According to the lab report, the sixteen (16) above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 22.

328. Allstate was billed $1,081.32 relative to these sixteen (16) units of quantitative testing that were unnecessarily performed to confirm negative qualitative test results. *See* Exhibit 23.

329. Ameritox submitted claims for payment and accompanying medical records relative to J.M. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

330. Allstate relied upon Ameritox's submissions in adjusting the claims.

d. J.B. (Claim No. 0154668453)

331. Patient J.B. purportedly gave a urine sample on June 14, 2012 in the Commonwealth of Kentucky that was tested by Ameritox.

332. Ameritox submitted a report detailing the lab results of J.B.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 24.

333. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

334. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

335. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

336. According to J.B.'s lab report, qualitative testing for the following nine (9) drug categories yielded a "negative" result: cocaine (benzoylecgonine), MDMA, phencyclidine, fentanyl, methadone, its metabolite EDDP, propoxyphene, barbiturates, and amphetamines. Id.

337. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

338. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following eight (8) charges: two units of 82145 (amphetamines or methamphetamine); 82205 (barbiturates); 82520 (cocaine or its metabolite), two units of 83840 (methadone); 83925 (opiate(s), drug and metabolites, each procedure), which appears to be applicable to fentanyl; and 83992 (phencyclidine). *See* Exhibit 25.

339. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

340. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

341. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in J.B.'s specimen).

342. According to the lab report, the above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 24.

343. Allstate was billed $418.90 relative to these eight (8) units of quantitative testing that were unnecessarily performed to confirm negative qualitative test results. *See* Exhibit 25.

344. Ameritox submitted claims for payment and accompanying medical records relative to J.B. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

345. Allstate relied upon Ameritox's submissions in adjusting the claims.

e. A.B. (Claim No. Z6079482)

346. Patient A.B. purportedly gave a urine sample on September 24, 2012 in the State of New York that was tested by Ameritox.

347. Ameritox submitted a report detailing the lab results of A.B.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 26.

348. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

349. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

350. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

351. According to A.B.'s lab report, qualitative testing for the following thirteen (13) drugs/drug classes categories yielded a "negative" result: cocaine (benzoylecgonine), MDMA, phencyclidine, opiates, oxycodone/oxymorphone, heroin, fentanyl, methadone, its metabolite EDDP, benzodiazepines, barbiturates, carisprodol, and amphetamines. Id.

352. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

353. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following eleven (11) charges: 80154 (benzodiazepines); two units of 82145 (amphetamines or methamphetamine); 82520 (cocaine or its metabolite); 82205 (barbiturates); two units of 83840 (methadone); three units of 83925 (opiate(s), drug and metabolites, each procedure), which appears to be applicable to opiates, oxycodone/oxymorphone and fentanyl; and 83992 (phencyclidine). *See* Exhibit 27.

354. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

355. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

356. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in A.B.'s specimen).

357. According to the lab report, the eleven (8) above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 26.

358. Allstate was billed $605.60 relative to these eleven (11) units of quantitative testing that were performed to confirm negative qualitative test results. *See* Exhibit 27.

359. Ameritox submitted claims for payment and accompanying medical records relative to A.B. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

360. Allstate relied upon Ameritox's submissions in adjusting the claims.

f. L.T. (Claim No. 08129857)

361. Patient L.T. purportedly gave a urine sample on August 23, 2011 in the State of New Jersey that was tested by Ameritox.

362. Ameritox submitted a report detailing the lab results of L.T.'s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 28.

363. In the report, Ameritox identifies the categories of drugs tested and the corresponding qualitative test result (listed as either "negative" or "positive") in the "Lab Result (Qualitative)" column. Id.

364. The column immediately to the right of the "Lab Result (Qualitative)" column is entitled "Lab Result (ng/mL)" in which the quantitative test result (expressed as a discrete numeric value) is listed, if applicable. Id.

365. Where the "Lab Result (Qualitative)" column lists "negative" as the qualitative result, and in the absence of extenuating circumstances which must be documented by the treating provider which were not present here, confirmatory testing of any type (qualitative or quantitative) was not necessary.

366. According to L.T.'s lab report, qualitative testing for the following eleven (11) drug categories yielded a "negative" result: cocaine (benzoylecgonine), MDMA, phencyclidine, oxycodone/oxymorphone, buprenorphine, methadone, its metabolite EDDP, propoxyphene, benzodiazepines, barbiturates, and amphetamines. Id.

367. As such, and in the absence of a documented request from the treating provider requesting confirmation (which was not present here), it was not necessary for Ameritox to confirm the negative qualitative results.

368. Nonetheless, Ameritox submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following nine (9) charges: 80154 (benzodiazepines); two units of 82145 (amphetamines or methamphetamine); 82205 (barbiturates); 82520 (cocaine or its metabolite); one unit of 83925 (opiate(s), drug and metabolites, each procedure), which appears to be applicable to oxycodone/oxymorphone, two units of 83840 (methadone or its metabolite); and 83992 (phencyclidine). *See* Exhibit 29.

369. The HICF also contains a charge for HCPCS G0431, evidencing that qualitative testing was done, which is consistent with Ameritox's lab report. Id.

370. As the above drugs were initially qualitatively tested by Ameritox and were found to be "negative," Ameritox unnecessarily performed quantitative confirmation testing to verify the results.

371. In stark contrast to the statement on Ameritox's website, the defendants in fact did bill for confirmatory quantitative testing of drugs/drug classes that were qualitatively determined to be negative (or not present in L.T.'s specimen).

372. According to the lab report, the nine (9) above-itemized drugs were initially determined to be "negative," thus any subsequent confirmation testing for these specific drugs was medically unnecessary. *See* Exhibit 28.

373. Allstate was billed approximately $485.36 relative to these nine (9) units of quantitative testing that were unnecessarily performed to confirm negative qualitative test results. *See* Exhibit 29.

374. Ameritox submitted claims for payment and accompanying medical records relative to L.T.to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

375. Allstate relied upon Ameritox's submissions in adjusting the claims.

D. UNNECESSARY QUANTITATIVE CONFIRMATION TESTING

376. As discussed above, the defendants almost always unnecessarily confirmed negative qualitative/screening testing results.

377. The defendants also unnecessarily performed quantitative confirmatory testing on positive qualitative/screening testing results where the standard of care provides that qualitative confirmation is typically sufficient.

378. In a pain management setting (as existed with respect to the Allstate insureds at issue herein who were purportedly injured in motor vehicle accidents), and in the absence of suspected acute intoxication and/or suspected overdose, the quantitative testing of illicit drugs and prescribed/non-prescribed drugs is not medically necessary.

379. If an unexpected substance is found in the urine screen test (i.e., the result is reported as "positive"), it should be confirmed by a different qualitative – not quantitative – urine drug test method.

380. On October 30, 2000, the AMA added CPT Code 80102 ("[d]rug confirmation, each procedure") to bill for qualitative confirmatory testing performed.

381. However, the defendants did not bill Allstate for qualitative confirmatory testing, which is represented by CPT Code 80102, until April 17, 2015, (discussed in greater detail under the fraudulent billing practice section *infra*).

382. As discussed below, Ameritox required its client providers to choose a panel with a minimum number of urine drug tests that would be performed on every patient specimen.

383. None of these panels included qualitative confirmatory testing within their parameters.

384. Thus, Ameritox never gave the referring provider the option to choose qualitative confirmatory testing, but instead made the decision that a referring provider using its laboratory urine drug testing services for confirmatory testing must use quantitative confirmation testing.

385. Ameritox cannot lawfully make decisions regarding what are reasonably necessary urine drug testing services for a patient.

386. As noted above, quantitative urine drug testing is almost always reimbursed at a higher rate than qualitative testing.

387. Thus, there is little question why the defendants routinely chose to perform quantitative confirmation testing instead of qualitative.

388. However, a laboratory's decision to perform more expensive quantitative confirmation testing in the absence of necessity and/or a patient-specific documented request from the treating provider does not support billing for quantitative confirmation testing.

389. In almost every instance where the defendants billed Allstate for quantitative confirmatory testing, there is no reason why the defendants did not comply with the industry standard of care and utilize qualitative confirmatory testing.

390. Thus, the defendants fraudulently billed Allstate for unnecessary quantitative confirmation testing.

E. DUPLICATIVE URINE DRUG SCREEN TESTING

391. As discussed above, referring providers were able to (and often did) perform urine drug screen testing in their offices to monitor for the presence of drugs in a patient's urine specimen.

392. The referring provider billed Allstate for the in-office testing, called point-of-care testing (POCT).

393. Upon information and belief, when a patient submitted a urine specimen to the treating provider, the treating provider tested one portion of the specimen in his or her office and forwarded the other portion to Ameritox for testing.

394. Thus, urine drug screen testing on the same urine sample was done by both the treating provider and Ameritox.

395. Ameritox was aware that many treating providers were performing POCT as Ameritox often provided the testing cups to the treating providers (usually for free or significantly

below market value to entice the provider to refer the urine sample to Ameritox for a battery of testing, as discussed *supra*).

396. Moreover, Ameritox's standard requisition forms contain an area for treating providers to record the results of POCT when submitting a specimen to Ameritox.

397. Where urine drug screen testing had already occurred at the point-of-care level for the same drug and/or its metabolite, there was no need for Ameritox to perform an additional urine drug screen test.

398. Yet the defendants billed Allstate for urine drug screen testing on those same drugs/drug classes for every patient at issue herein where POCT occurred.

399. Whenever Ameritox tested for drugs that had already been tested at the point-of-care level, Ameritox's testing was duplicative and unnecessary.

400. According to Ameritox's standard testing procedure, "[a]n initial Enzyme Immunoassay (EIA) test screens for the presence of opiates, benzodiazepines, illicits and other prescribed or non-prescribed medications. The EIA uses antigen antibody reactions to provide fast, reliable results." *See* Exhibit 17.

401. Thus, it was standard operating procedure for Ameritox to perform a screening immunoassay test on the specimens it received without any consideration as to whether comparable urine drug screen testing had already been performed on the same urine sample by the referring provider at the point-of-care level.

402. Ameritox was aware of the results of the POCT because it was documented on the requisition form submitted to Ameritox at the time of each specimen referral.

403. The defendants were not only aware that referring providers often performed POCT, the defendants encouraged providers to perform POCT and often provided them with free specimen cups.

404. Necessity is not established where Ameritox repeated screening-type testing on the same urine sample that had already undergone a screening test for the same drugs.

405. The defendants knew that this redundant screening testing was neither reasonable nor necessary.

406. Instead, consistent with the standard of care for clinical laboratories, Ameritox should have performed qualitative confirmatory testing on those specific drugs/drug classes indicated by the referring provider (i.e., those which the referring provider had a specific clinical reason to refer for additional testing).

407. The defendants routinely submitted reimbursement claims to Allstate seeking payment for the duplicative screening tests performed for the purpose of substantially inflating Ameritox's profits.

408. Ameritox's standard testing process ensured that the testing of each specimen submitted by the referring provider was based on Ameritox's profit-driven protocols and not based on the specific needs of the patient or the real-time concerns of the referring provider.

409. This practice allowed the defendants to perform duplicative and medically unnecessary tests on a single specimen, thereby increasing Ameritox's profit without providing any benefit or clinical utility to the patient or referring provider.

410. Ameritox's practice of repeating screening testing for the same drug or its metabolite as had occurred at the point-of-care level was exacerbated by the fact that Ameritox

also frequently performed expensive and unnecessary quantitative confirmatory testing on the same specimen, as discussed *supra*.

411. Thus, the same specimen was often tested three separate times: once at the point-of-care level, qualitative/screening testing by Ameritox, and confirmatory quantitative testing by Ameritox.

412. It is almost never necessary to test the same specimen three separate times (especially where two of the times involve the same testing methodology) absent highly specific and specialized circumstances which must be documented by the treating physician and which are not present with respect to Allstate insureds/patients at issue in this Complaint.

413. Thus, in a multitude of ways, the duplicative testing done by the defendants and billed to Allstate was unnecessary.

F. TESTING NOT ORDERED BY THE REFERRING PROVIDER

414. As part of Ameritox's standard testing process, it performed "specimen validity testing" on each specimen it was referred from treating providers.

415. Specimen validity testing is the evaluation of a specimen to determine if it is consistent with normal human urine.

416. If ordered by a licensed healthcare professional, specimen validity testing may be considered appropriate and necessary (depending on patient-specific circumstances).

417. Ameritox, however, performed specimen validity testing as a matter of course, and without the input and not at the request of the referring provider.

418. Ameritox sought payment from Allstate for specimen validity testing encompassed by the following three (3) CPT Codes: 83986 (pH; body fluid, not otherwise specified); 84311

(spectrophotometry, analyte not elsewhere specified), seeking to quantify specific gravity; and 82570 (creatinine), for each urine specimen it tested.

419. The standard of care is clear that only testing ordered by a licensed healthcare professional can be considered necessary and that laboratories like Ameritox cannot determine what is a reasonable test to be performed.

420. The federal government, for example, instructs that "[o]nly those tests that are ordered by an authorized individual or physician, are performed and meet Medicare's conditions of coverage are reimbursable by Medicare."[4] *See* Exhibit 30 at 45080-45081.

421. Ameritox, however, automatically performed (and billed Allstate for) the tests represented by CPT Codes 83986, 84311, and 82570 on each specimen it received without a determination from the referring provider as to whether such testing was medically necessary.

422. In fact, Ameritox dictated to the treating provider that specimen validity testing would be performed on each specimen received without allowing each provider to determine whether specimen validity testing was medically necessary for each specific specimen/patient.

423. Ameritox's recurring order form states that "pH, Specific Gravity, Creatinine . . . **must** be done on all specimens." *See* Exhibit 31 (emphasis added).

424. Thus, Ameritox did not offer treating providers a choice as to whether specimen validity testing should be performed, but rather instructed that it must be done if the provider wanted to use Ameritox's laboratory services.

425. As such, Ameritox performed testing that was never specifically ordered by the referring provider, rendering such testing unnecessary and unjustified.

[4] Ameritox has affirmatively stated that "ethics are concrete and not subject to local competitive whims" and that "[e]thical Standards are for the Nation – Not State-by-State." *See* Exhibit 17. Ameritox also touts that its programs have been reviewed by the Office of Inspector General (OIG) and that Ameritox works closely with the OIG. Id.

426. Allstate is not required to pay for testing that was (1) not ordered and deemed necessary by a licensed healthcare provider and (2) performed by Ameritox for the sole purpose of increasing its profits.

G. AMERITOX'S TESTING PROCEDURES AND FORMS PROMOTE UNNECESSARY TESTING

427. As detailed above, the defendants had the singular goal of generating as many claims as possible against payors like Allstate and resorted to billing for services not rendered and billing for unnecessary testing to achieve this goal.

428. The defendants were aided in attaining its goal by the standard procedures and forms that they established and mandated be used by all treating providers who referred specimens to Ameritox for urine drug testing, including recurring order and requisition forms.

429. The defendants required that each referring provider complete a "recurring order" form, which was kept on file with Ameritox.

430. In the recurring order form, the defendants require that treating providers choose one of several "panel preferences." *See* Exhibit 31.

431. Each panel preference contains several categories of drugs that will automatically be tested by Ameritox once the treating provider has chosen that panel.

432. The panel preferences range from a minimum of eight (8) drugs to be tested for (Panel 8) to as many as fourteen (14) drugs to be tested for (Panel 13). Id.

433. The recurring order form – and the panel preferences contained therein – is chosen by the referring provider at the commencement of the relationship between Ameritox and the referring provider.

434. The recurring order form – and the panel preferences contained therein – is necessarily not patient-specific as it is established prior to the patient's urine drug testing referral.

435. The recurring order form remains on file with Ameritox and serves as the default for tests to be done by Ameritox unless the referring provider opts for a different panel preference on the requisition form that it submits to Ameritox with each urine sample.

436. A requisition form accompanies each urine sample referred to Ameritox for testing.

437. Ameritox's requisition forms contain an area (Box 6) where the referring provider can "change [his/her] Panel Preference for this sample only." *See* Exhibit 32 (emphasis added).

438. However, the referring provider must choose a minimum panel of tests to be done and cannot choose to have a fewer number of individual drugs tested than found in the panel.

439. In other words, Ameritox requires that a minimum number of drugs/drug classes be tested (i.e., every drug within the chosen panel) regardless of whether the referring provider believes that all of the tests within that panel are necessary to the care of the specific patient whose specimen is being referred. *See* Exhibit 31.

440. The requisition form confirms that Ameritox will default to test the panel preference chosen by the treating provider in the recurring order form without explicit instruction otherwise: "Making no notation in this box means this sample will be tested using your Panel Preference currently on file listed above." *See* Exhibit 32.

441. The requisition form allows the treating provider to choose "Additional Tests" (Box 4), but does not provide the option to reduce the number of tests to be performed. Id.

442. Ameritox's standard requisition form also provides that several drugs tested at the point-of-care will be automatically confirmed by Ameritox regardless of whether the POCT resulted in a positive or negative result.

443. As discussed above, there is rarely a reason to confirm an expected negative screening result and even then a patient-specific reason to confirm must be documented.

444. The decision to perform confirmation testing before the results of the qualitative/screening test are known stands in stark contrast to Ameritox's own representation that "Ameritox, unlike a San Diego company, does not recommend customers retest negative drug samples much less make it a standing practice to retest all negative drug samples." *See* Exhibit 16.

445. Ameritox's use of panel preferences and preselected requisition forms also violate established standards of practice that demand that only medically necessary urine drug testing be performed, as decided on a patient-by-patient and visit-by-visit basis by a licensed healthcare professional.

446. The Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") has formulated a compliance program providing clear guidance to clinical laboratories to reduce fraud and abuse within their organizations and "assist clinical laboratories in developing effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans." *See* Exhibit 30 at 45077.

447. With respect to panel preferences, the OIG has stated that "standing orders . . . too often . . . have led to abusive practices." Id. at 45081; *see also* Exhibits 7 and 10.

448. Specifically, the OIG has stated that "[l]aboratories routinely offer customized profiles and panels to physicians. Physicians often order the profile/panel containing the test they need rather than specifying just the needed test(s). Profiles and panels desensitize physician concerns about the medical necessity of the laboratory tests they are ordering. Moreover, panels and profiles contribute to unbundling billing schemes and contribute to the ordering of medically unnecessary laboratory tests." *See* Exhibit 33.

449. With respect to requisition forms, the OIG has stated that "[t]he laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill." *See* Exhibit 30 at 45079.

450. As discussed above, instead of abiding by the OIG (and other) guidelines, Ameritox's requisition form instead is designed to increase the number of tests performed and ignores considerations about medical necessity.

451. This is evidenced by the default to the referring provider's panel preference on file (which necessarily cannot be patient-specific as it was decided before the patient was known to the referring provider), by the preselected option to confirm POCT results without knowing whether the same were positive or negative, and by the requisition form's failure to allow the referring provider to subtract any tests from the preselected panel preference (though the provider is given the option to add tests).

452. In addition to forcing referring providers to choose a panel where a minimum of eight (8) drugs would always be tested, the defendants further removed decisions of necessity from the treating providers by not customizing the panel preferences to the specific geographic region of each referring provider.

453. The decision regarding which drugs of abuse to test for is often based on what drugs (both prescription and illicit) are available on the street in the geographic region from which the testing is ordered.

454. By not tailoring the panel preferences they demanded be used to even the geographic locations of referring providers (let alone the needs of each specific provider and

patient), the defendants further encouraged unnecessary and excessive urine drug testing by their use of predetermined testing procedures and forms.

455. "Laboratory compliance programs, to be effective, should communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition. Laboratories should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable, and necessary for the beneficiary, given his or her clinical condition." *See* Exhibit 30 at 45079.

456. There is no question that the defendants failed to abide by this directive and the standard of care governing clinical laboratories like Ameritox.

457. Instead of taking steps to ensure that it was only submitting claims for necessary drug testing, Ameritox (by and through its officers and managers, including Backer, Leider, Walton, Lopes, and Zimmerman) intentionally worked to increase the number of medically unnecessary tests it performed and, therefore, billed to payors like Allstate.

458. First, Ameritox required treating providers to choose a panel preference that mandated that at least eight (8) drugs be tested every time the referring provider referred a urine sample to Ameritox.

459. Second, Ameritox's requisition form preselected options for confirmation testing that pre-dated and did not take into account the results of the POCT.

460. Finally, as detailed *supra*, the defendants pressured sales representatives to coerce treating providers to choose the panel containing the most drugs to be tested for the sole purpose of generating additional profit and without regard for medical necessity.

461. For all of these reasons, the requisition forms, recurring order forms, and sales tactics developed and used by the defendants facilitated and encouraged excessive and unnecessary urine drug testing.

462. Allstate's main competitor in the urine drug testing market recently agreed to pay the government almost a quarter of a billion dollars to resolve very similar allegations that standing order and requisition forms were utilized to facilitate unnecessary testing, including the following specific allegations:

a. "A core element of Millennium's business model was the use of physician standing order forms. Millennium created the forms as part of its plan to direct physicians to establish protocols for laboratory testing to be performed on all of their patients – usually, at a minimum, a dozen or more drug tests – regardless of each patient's individualized need and condition." *See* Exhibit 10, ¶ 88.

b. "Millennium expected not only that physicians would have a Standing Order or Custom Profile, but also required certain testing thresholds, so that Millennium could make more money. Millennium refused to do business with accounts that failed to meet these thresholds." Id. at ¶ 95.

c. "Millennium employees routinely submitted completed Custom Profile forms to headquarters for processing . . . and often filled out information on the Custom Profile forms themselves." Id. at ¶ 98 (internal citation omitted).

d. "Millennium even processed specimens under customers' Custom Profiles in instances where the 'Use Custom Profile' box in Section A of the requisition form was left blank." Id. at ¶ 99.

See Exhibit 7.

VII. FRAUDULENT BILLING PRACTICES

463. Providers like Ameritox have a responsibility to select and submit the billing code (CPT or HCPCS) that accurately and truthfully identifies the services performed and the complexity involved in rendering those services.

464. Ameritox, by and through the individual defendants, failed to meet its responsibility and instead submitted demands for payment to Allstate for (1) unnecessary quantitative testing, (2) duplicative qualitative/screening testing, and (3) testing that was not ordered by the treating provider.

465. Ameritox also submitted claims to Allstate through the U.S. Mail for testing billed using a number of fraudulent billing practices, including several distinct types of unbundling and improperly billing multiple units of the same billing code on the same date of service.

A. UNBUNDLING OF SPECIMEN VALIDITY TESTING

466. Specimen validity testing is the evaluation of a specimen to determine if it is consistent with normal human urine.

467. As discussed *supra*, Ameritox's standard testing process included the performance of "specimen validity testing" on each specimen it received from referring providers.

468. In fact, Ameritox dictated to the treating provider that specimen validity testing would be performed on each specimen received without allowing each provider to determine whether specimen validity testing was medically necessary for each specific specimen/patient.

469. Ameritox's recurring order form states that "pH, Specific Gravity, Creatinine . . . **must** be done on all specimens." *See* Exhibit 31 (emphasis added).

470. Ameritox sought payment from Allstate for specimen validity testing encompassed by the following three (3) CPT Codes: 83986 (pH; body fluid, not otherwise specified); 84311 (spectrophotometry, analyte not elsewhere specified), seeking to quantify specific gravity; and 82570 (creatinine), for each urine specimen it tested.

471. However, only CPT Code 82570 was appropriate (assuming the specimen validity testing was determined to be medically necessary by the referring physician) for Ameritox to bill for its specimen validity testing.

472. CPT Code 82570 (creatinine; other source) indicates that testing for creatinine was performed on a urine specimen.

473. In fact, CPT Codes 83986 and 84311 are not appropriate for inclusion in urine specimen validity testing because they are both meant to be used for the testing of bodily fluids other than urine.

474. Specifically, CPT Code 83986 states that it is to be used when testing for "pH [of a] body fluid, not otherwise specified" and CPT Code 84311 is to be used for "spectrophotometry [for] analyte not elsewhere specified" (testing for specific gravity).

475. The terms "not otherwise specified" and "not elsewhere specified" indicate that CPT Codes 83986 and 84311, respectively, are only to be billed for tests on fluids or analytes not already referenced in a specific CPT Code.

476. CPT Code 81003 is an all-encompassing urinalysis code that includes testing for "bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, **pH**, protein, **specific gravity**,

urobilinogen, any number of these constituents; automated, without microscopy" (emphasis added).

477. Specific gravity and pH testing on urine specimens are specifically covered by the all-inclusive CPT Code 81003.

478. The AMA introduced CPT Code 81003 in 1993 and it has since remained in effect at all times relevant to this Complaint.

479. The defendants were helped in their unbundling scheme by the creation and use of Ameritox's requisition form and recurring order.

480. The OIG has stated that "panels and profiles contribute to unbundling billing schemes and contribute to the ordering of medically unnecessary laboratory tests." *See* Exhibit 33.

481. Ameritox submitted unbundled specimen validity charges in excess of 97% of the claims at issue in this Complaint. *See* Exhibits 1 through 6.

482. Each and every instance of Ameritox billing Allstate CPT Codes 83986 and 84311 constitutes two separate instances of unbundling. *See* Exhibit 34.

483. The prevalence of the defendants' unbundling in this regard evidences that it was a regular practice that was knowingly and intentionally done.

484. In fact, Ameritox openly confirms that it unbundles its specimen validity charges. *See* Exhibit 35.

485. Unbundling that is done knowingly and intentionally constitutes a fraudulent billing practice.

B. UNBUNDLING OF G0431 AND G0434

486. For several of the claims at issue in this Complaint, Ameritox submitted reimbursement claims to Allstate through the U.S. Mail seeking payment for services billed by HCPCS Codes G0431 and G0434 on the same date of service.

487. Effective January 1, 2011, HCPCS G0431 is to be billed for "[d]rug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter."

488. Effective January 1, 2011, HCPCS G0434 is to be billed for "[d]rug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter."

489. As of October 1, 2012, HCPCS G0434 cannot be billed on the same date of service for the same patient as HCPCS G0431.

490. The Centers for Medicare & Medicaid Services ("CMS") instituted the National Correct Coding Initiative ("NCCI") to promote national correct coding methodologies and to control improper coding leading to inappropriate payment for Medicare Part B claims.

491. There are two NCCI edit tables: "Column One/Column Two Correct Coding Edit Table" and "Mutually Exclusive Edit Table."

492. Each edit table has a Column One and Column Two HCPCS/CPT Code.

493. Each edit table contains edits, which are pairs of HCPCS/CPT Codes that cannot be reported together because the services (and reimbursement) of the Column Two code is subsumed by the services (and reimbursement) for the Column One code.

494. Violation of the edits (billing a Column One code and a Column Two code on the same day for the same claimant) is known as "unbundling," which occurs when a provider bills

separately for individual components of a procedure which are included in another billing code also billed for the same date of service.

495. If a provider reports the two codes of an edit pair, the Column Two code is denied and the Column One code is eligible for payment.

496. Effective October 1, 2012, HCPCS G0431 and G0434 can never be billed for the same patient on the same date of service under any circumstances.

497. As stated by CMS, "there are no circumstances in which both procedures of the code pair [i.e., G0431 and G0434] should be paid for the same beneficiary on the same day by the same provider."

498. The submission of both of these codes for the same patient on the same date of service represents unbundling.

499. Here, the defendants submitted or caused to be submitted to Allstate at least 115 bills containing both HCPCS G0431 and G0434 for the same patient on the same date of service after October 1, 2012, as demonstrated by the representative patients on the chart annexed hereto at Exhibit 36.

500. As documented on the chart annexed hereto at Exhibit 36, the defendants engaged in at least 115 instances of unbundling for HCPCS G0431 and G0434 since October 1, 2012 (i.e., 115 separate instances where HCPCS G0431 and G0434 were billed relative to the same patient on the same date of service).

501. The prevalence of the defendants' unbundling in this regard evidences that it was a regular practice that was knowingly and intentionally done.

502. Unbundling that is done knowingly and intentionally constitutes a fraudulent billing practice.

C. UNBUNDLING OF G0431 AND 83516

503. For several of the claims at issue in the within Complaint, Ameritox submitted reimbursement claims to Allstate through the U.S. Mail seeking payment for services billed by HCPCS G0431 and CPT Code 83516 on the same date of service.

504. As noted above, effective January 1, 2011, HCPCS G0431 is to be billed for "[d]rug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter."

505. Also effective January 1, 2011, the description for CPT Code 83516 was defined as "[i]mmunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semi-quantitative, multiple step method."

506. As discussed above, CMS and the NCCI have established edit tables to promote national correct coding methodologies and to control improper coding, including defining circumstances where it is inappropriate to bill certain CPT/HCPCS Codes for the same patient on the same date of service.

507. As of January 1, 2011, CPT Code 83516 is considered a Column Two code to HCPCS G0431 when HCPCS G0431 is billed during the same patient encounter.

508. Thus, as of January 1, 2011, CPT Code 83516 cannot be billed on the same date of service for the same patient as HCPCS G0431 unless certain criteria are met.

509. These criteria were almost never present with respect to the Allstate insureds/patients at issue in this Complaint.

510. Where CPT Code 83516 is used to report the performance of a qualitative urine drug test, the criteria for separate reporting established by CMS and the NCCI is not met.

511. In other words, for dates of service after January 1, 2011, almost every time HCPCS G0431 and CPT Code 83516 were billed during the same date of service, CPT Code 83516 was not compensable because HCPCS G0431 is considered the Column One code and the services designated by CPT code 83516 were already embedded within the services designated by HCPCS G0431.

512. The defendants knowingly and fraudulently submitted reimbursement claims to Allstate seeking payment for HCPCS G0431 and CPT Code 83516 without the proper criteria being met for the same patient on the same date of service after January 1, 2011 at least 265 times, as detailed on the chart annexed hereto at Exhibit 37.

513. The defendants' behavior constitutes a pervasive pattern of unbundling.

514. Unbundling, if done with knowledge and intent, as it was by the defendants here on at least 265 occasions, is an example of a fraudulent billing practice.

D. AMERITOX BILLED ALLSTATE USING DELETED CPT CODES

515. The AMA made several changes in the Pathology and Laboratory 80000 series code section of the CPT Code effective January 1, 2015, including but not limited to the deletion of forty-seven (47) CPT Codes.

516. Relevant to this Complaint, the AMA deleted CPT Codes 80101 (drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class); 80102 (drug confirmation, each procedure); 80154 (benzodiazepines); 82055 (alcohol (ethanol); any specimen except breath); 82145 (amphetamines or methamphetamine); 82205 (barbiturates); 82520 (cocaine or its metabolite); 83805 (meprobamate); 83840 (methadone); 83925 (opiate(s), drug and metabolites, each procedure); and HCPCS G0431 (drug screen, qualitative; multiple drug

classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter), as of January 1, 2015.

517. Providers like Ameritox have a responsibility to select and submit the billing code (CPT or HCPCS) that accurately and truthfully identifies the services performed and the complexity involved in rendering those services.

518. However, Ameritox disregarded its obligation to submit claims consistent with the AMA's CPT Code Book.

519. Instead, as of January 1, 2015, Ameritox fraudulently billed Allstate using deleted CPT Codes on 112 individual dates of service and in excess of $150,000. *See* Exhibit 38.

520. Allstate is not required to compensate the defendants for their fraudulent billing of deleted CPT Codes as of January 1, 2015.

VIII. SPECIFIC ALLEGATIONS OF MISREPRESENTATIONS MADE TO AND RELIED ON BY ALLSTATE

A. MISREPRESENTATIONS BY THE DEFENDANTS

521. To induce Allstate to pay promptly their fraudulent charges for (1) unnecessary testing, (2) duplicative testing, and (3) fraudulently billed testing, the defendants submitted or caused to be submitted to Allstate documentation, including but not limited to HICFs/bills, invoices, and medical records (lab reports) that materially misrepresented that the drug testing performed was actually provided and was medically necessary as required by the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law.

522. As discussed throughout this pleading, the full extent of misrepresentations contained in the HICFs/bills submitted to Allstate by the defendants only became known to Allstate upon its investigation of the defendants, including discovery of (1) the defendants'

pervasive use of kickbacks, in-office specimen processors, and aggressive sales tactics to induce unnecessary and excessive referrals to Ameritox, (2) the defendants' practice of targeting patients with specific payor/insurance sources, such as Allstate, for the purpose of inflating bills that the defendants believed were more likely to be paid, (3) the defendants' mandate that all referring providers must select a minimum panel of drugs/drug classes to be tested by Ameritox and the defendants' refusal to permit referring providers to request that only necessary urine drug testing be done, and (4) the defendants' failures to abide by their own representations, including those made on Ameritox's website (detailed above).

523. None of these facts is evident within the four corners of the documents submitted to Allstate by the defendants and upon which Allstate relied in adjusting the claims and tendering payment.

524. Claims under the No-Fault laws of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky can only be submitted for medically necessary treatment and treatment that actually occurred.

525. Thus, every time Ameritox, at the direction of its officers and managers Backer, Leider, Walton, Lopes, and Zimmerman, submitted bills and lab reports to Allstate supporting its claims for No-Fault benefits, the defendants necessarily warranted that such bills and medical records related to necessary testing that was actually performed.

526. In fact, however, the urine drug testing billed for by Ameritox (at the direction of Backer, Leider, Walton, Lopes, and Zimmerman) was rarely necessary, including several tests that were done without a determination of medical necessity by a licensed healthcare provider.

527. The full extent of the defendants' fraudulent acts – including billing for performing unnecessary and excessive confirmation testing, performing duplicative tests, and using fraudulent

billing practices – was not and could not have been known to Allstate until it commenced its investigation of the defendants shortly before filing the within Complaint.

528. In particular, the defendants took advantage of the technical complexity and esoteric nature of the urine drug testing Ameritox allegedly performed to mask their fraudulent billing.

529. Moreover, Allstate is obligated to pay or deny claims received from providers within a small period of time.

530. As such, and given the number of bills received by Allstate every day, Allstate cannot scrutinize every bill it receives and must at times rely on the submitting provider to comply with the law and submit only valid claims for No-Fault benefits.

531. This is particularly true where the provider (here, Ameritox) submits claims for specialized services such as clinical laboratory urine drug testing, which require a level of expertise to perform and bill for that exceeds the knowledge of the typical insurance claims adjuster.

532. The fact of billing for unnecessary/duplicative urine drug testing is present with respect to every claim at issue herein.

533. Thus, each claim for payment (and accompanying medical records) under the No-Fault laws of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky sent to Allstate by or at the direction of the defendants constitutes a misrepresentation because the treatment underlying the claim was not actually provided and/or was not medically necessary, both of which must be present in order for a service to be compensable under the No-Fault laws of these six states.

534. The urine drug testing rendered by, or at the direction of, the defendants was not lawful and every claim for payment submitted to Allstate through the U.S. Mail misrepresented this fact.

535. Moreover, each HICF submitted to Allstate by or on behalf of the defendants contained the following notation: "NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

536. The HICFs also contained the (electronic) signature of the treating provider, Backer.

537. Through the submission of lab reports, invoices, HICFs, and other medical documentation to Allstate via the U.S. Mail, the defendants attested to the fact and medical necessity of the drug testing for which they billed Allstate.

538. As Ameritox did not render reasonably necessary drug testing in addition to engaging in other fraudulent billing practices, each HICF and accompanying documentation submitted by Ameritox (at the direction and with the knowledge of its officers and managers Backer, Leider, Walton, Lopes, and Zimmerman) to Allstate constitutes a material misrepresentation.

539. Backer was Ameritox's Vice President of Toxicology and the person who signed the HICFs submitted to Allstate, attesting to the fact and necessity of the urine drug testing billed for on the HICF.

540. Leider was Ameritox's Chief Medical Officer and Senior Vice President in charge of Ameritox's clinical research program and provider relations (i.e., obtaining referrals from treating providers) during the majority of the time period at issue in this Complaint.

541. Walton is Ameritox's Chief Executive Officer charged with overseeing the entire company, including its sales representatives, referral strategies, and standard testing and billing procedures.

542. Lopes likewise oversaw the entire Ameritox operation during his time as Chief Executive Officer and continues to advise and direct the company in his present role as Senior Advisor.

543. Zimmerman is Ameritox's Chief Operating Officer and Chief Laboratory Officer and has admitted under oath that he was responsible for Ameritox's specimen processor program and has further stated that he develops laboratory testing strategy.

544. As the individuals in charge of and responsible for Ameritox, Backer, Leider, Walton, Lopes, and Zimmerman are directly responsible for the misrepresentations made to Allstate by Ameritox.

545. Backer, Leider, Walton, Lopes, and Zimmerman managed and operated every aspect of Ameritox from pressuring sales representatives to obtain as many referrals as possible (including through the use of kickbacks), to establishing the pattern and protocol whereby urine samples were tested for as many drugs as possible regardless of the necessity of such testing, to permitting Ameritox to lie about the tests it performed, to encouraging fraudulent billing practices designed solely to increase the amount billed to Allstate.

546. As the managers and operators of Ameritox, Backer, Leider, Walton, Lopes, and Zimmerman ordered and encouraged that misrepresentations be made to Allstate.

547. As a licensed healthcare professional, Backer was obligated, legally and ethically, to act honestly, with integrity, and in accordance with his professional oaths and pledges.

548. Each misrepresentation made by Backer was in violation of his legal and ethical obligations as a healthcare professional.

549. As a licensed medical doctor, Leider was obligated, legally and ethically, to act honestly, with integrity, and in accordance with his professional oaths and pledges.

550. Each misrepresentation made by Leider was in violation of his legal and ethical obligations as a medical professional.

B. ALLSTATE'S JUSTIFIABLE RELIANCE

551. At all relevant times, the defendants concealed from Allstate the truth regarding the fact and medical necessity of urine drug testing performed to prevent Allstate from discovering that the claims submitted by Ameritox were not compensable under the No-Fault laws of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky.

552. These misrepresentations include submitting false medical documentation, including HICFs, documenting the fact and necessity of urine drug testing in order to seek No-Fault benefits reimbursement.

553. Evidence of the fraudulent scheme detailed herein was not discovered until after patterns had emerged and Allstate began to investigate Ameritox and the individual defendants, revealing the true nature and full scope of the defendants' fraudulent scheme.

554. The defendants utilized their superior knowledge of the complex and specialized testing methodologies and billing practices associated with urine drug testing to mask the depth and breadth of their fraudulent billing scheme.

555. The defendants also published statements (especially on Ameritox's website) to mislead payors like Allstate into believing that they were only billing for urine drug testing that was actually done, and was medically necessary and reasonable.

556. Due to the defendants' material misrepresentations and other affirmative acts designed to conceal their fraudulent scheme from Allstate, Allstate did not and could not have discovered that its damages were attributable to fraud until shortly before filing the within Complaint.

557. In reasonable reliance on the defendants' misrepresentations, Allstate paid money to Ameritox to its detriment.

558. Allstate would not have paid these monies had the defendants provided true and accurate information about the fact and necessity of the drug testing provided.

559. As a result, Allstate has paid in excess of $1,283,212 in reasonable reliance on the false medical documentation and false representations regarding Ameritox's eligibility for reimbursement under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law.

IX. SPECIFIC ALLEGATIONS OF MAIL FRAUD RACKETEERING ACTIVITY

560. As discussed above, the defendants devised and agreed to enact a scheme to defraud Allstate by billing for services not provided and billing for unnecessary/excessive urine drug testing.

561. The drug testing purportedly provided by Ameritox was fraudulent because (1) it was performed pursuant to a preselected panel and not based on patients' individual clinical needs; (2) it was duplicative; and (3) it was billed using several improper billing practices, including unbundling.

562. Despite knowing that Ameritox's services were medically unnecessary and were improperly billed, and therefore not compensable under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and

Kentucky No-Fault Law, the defendants nonetheless submitted or caused to be submitted reimbursement claims to Allstate through the U.S. Mail seeking No-Fault benefit payments.

563. The objective of the scheme to defraud Allstate, which occurred throughout the period noted in Exhibit 39 was to collect No-Fault benefits under each of the various states' No-Fault Laws to which the defendants were not entitled because the drug testing rendered, if at all, was not medically necessary and because the defendants engaged in fraudulent billing practices.

564. This objective necessarily required the submission of claims to Allstate.

565. The defendants created, prepared, and submitted false medical documentation and placed the same in a post office and/or authorized depository for mail to be sent and delivered by the United States Postal Service.

566. All lab reports, documents, medical records, notes, HICFs, correspondence, and requests for payment in connection with the insurance claims referenced throughout this pleading traveled through the U.S. Mail.

567. Every automobile insurance claim detailed herein involved at least one use of the U.S. Mail, including the mailing of, among other things, the notice of claim, initial policies, insurance payments, medical records, bills, claims settlement checks, and return of the cancelled settlement drafts to the financial institution(s) from which the draft(s) were drawn, as well as the return of settlement draft duplicates to the insurance carrier for filing.

568. The fraudulent medical billing scheme detailed herein generated thousands of mailings.

569. A chart highlighting representative examples of mail fraud arising from the defendants' patient/business files is annexed hereto at Exhibit 39.

570. As detailed herein, the defendants also submitted, caused to be submitted, or knew medical documentation and claims for payment would be submitted to Allstate related to each exemplar patient discussed in this Complaint.

571. Backer is the Vice President of Toxicology for Ameritox and responsible for signing the HICFs prior to their submission to Allstate.

572. Thus, Backer, by and through his relationship with Ameritox, mailed or caused to be mailed documents, including lab reports, records, and bills, that materially misrepresented that Ameritox was (1) providing tests that were necessary, (2) providing tests that were ordered by a physician, and (3) using the proper billing codes for the tests purportedly performed.

573. Leider, as Ameritox's Chief Medical Officer, was likewise aware of and responsible for the misrepresentations contained in the medical documentation and bills mailed to Allstate.

574. Walton, Lopes, and Zimmerman, each a high-ranking officer of Ameritox, established and endorsed the testing and billing practices implemented and utilized by Ameritox, including misrepresenting the urine drug tests that were actually done and the necessity of all testing.

575. The defendants knew, and it was reasonably foreseeable, that Ameritox would submit false medical documentation, including the representative mailings detailed in Exhibit 39 annexed hereto, for No-Fault benefits reimbursement through the U.S. Mail related to the urine drug testing allegedly performed by Ameritox.

576. Indeed, it was within the ordinary course of business for Ameritox to submit claims for No-Fault benefits reimbursement to insurance carriers like Allstate through the U.S. Mail.

577. As the defendants agreed that Ameritox would use (and, in fact, did use) the mails in furtherance of their scheme to defraud Allstate by seeking payment for drug testing that was not compensable under the relevant No-Fault laws at issue herein, these defendants committed mail fraud, as defined in 18 U.S.C. § 1341.

578. A chart detailing representative examples of the mail fraud agreed to and perpetrated by the defendants is attached hereto at Exhibit 39 and includes specific information regarding the date, the sender, the recipient, and the content of such mailings.

579. As discussed above, the representative mailings identified in Exhibit 39 contained misrepresentations regarding the fact and necessity of the drug testing for which Allstate was billed.

580. Allstate reasonably relied on the submissions it received from the defendants through the U.S. Mail when adjusting the claims and tendering payment, including those representative submissions set out in Exhibit 39 and discussed as exemplar claims *supra*.

581. These payments were shared directly by all the defendants named herein.

582. As the defendants agreed to pursue the same criminal objective (namely, mail fraud), they committed a conspiracy within the meaning of the RICO Act, 18 U.S.C. § 1962(d), and are therefore jointly and severally liable for Allstate's damages.

X. DAMAGES

583. The pattern of fraudulent conduct by the defendants injured Allstate in its business and property by reason of the aforesaid violations of law.

584. Although it is not necessary for Allstate to calculate damages with specificity at this stage in the litigation, and Allstate's damages continue to accrue, Allstate's injury includes, but is not limited to, compensatory damages in excess of $1,283,212.

585. Exhibits 40 (New York), 41 (New Jersey), 42 (Michigan), 43 (Pennsylvania), 44 (Florida), and 45 (Kentucky), annexed hereto and incorporated herein as if fully set forth in their entirety, identify monies paid by Allstate to Ameritox in each state by date, payor, payee, patient claim number, check number, and amount.

586. Allstate's claim for compensatory damages, as set out in Exhibits 40 through 45, does not include payment made with respect to any Assigned Claim Facility claimant.

587. Allstate also seeks damages, in an amount to be determined at trial, related to the cost of investigation to uncover the fraudulent activities of the defendants and the cost of claims handling for claims submitted by Ameritox.

XI. CAUSES OF ACTION

COUNT I
VIOLATIONS OF 18 U.S.C. § 1962(c)
Against Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman

588. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

589. Ameritox constitutes an enterprise, as defined in 18 U.S.C. § 1961(4), engaged in, and the activities of which affect, interstate commerce.

590. In connection with each of the claims identified in the within Complaint, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman ("Count I defendants") intentionally caused to be prepared and mailed false medical documentation by Ameritox, or knew that such false medical documentation would be mailed in the ordinary course of Ameritox's business, or should have reasonably foreseen that the mailing of such false medical documentation by Ameritox would occur, in furtherance of the Count I defendants' scheme to defraud.

591. The Count I defendants employed, knew, or should have foreseen that two or more mailings to demand and/or receive payment from Allstate on certain dates, including but not limited to those dates identified in the chart annexed hereto as Exhibit 39.

592. Among other things, lab reports, medical records, bills, and invoices were delivered to Allstate thought the U.S. Mail.

593. Policies of insurance were delivered to insureds through the U.S. Mail.

594. Payments to Ameritox from Allstate were transmitted through the U.S. Mail.

595. As documented above, the Count I defendants repeatedly and intentionally submitted, caused to be submitted, or knew that documentation would be submitted to Allstate for urine drug testing that was purportedly performed by Ameritox to collect payment from Allstate under the personal injury protection benefits portion of the Allstate policies and applicable provisions of the No-Fault laws of the states at issue herein.

596. As a result of, and in reasonable reliance on, these misleading documents and misrepresentations, Allstate, by its agents and employees, issued drafts to Ameritox for the benefit of the Count I defendants that would not otherwise have been paid.

597. The Count I defendants' pattern of submitting, causing to be submitted, or knowing that fraudulent claims that appeared legitimate on their face would be submitted prevented Allstate from discovering the fraudulent scheme for a long period of time, thus enabling the defendants to continue their fraudulent scheme without detection.

598. The acts set forth above constitute indictable offenses pursuant to 18 U.S.C. § 1341 (mail fraud).

599. By mailing, or agreeing that the mails would be used to submit, numerous fraudulent claims in an ongoing scheme, the defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § 1962(c).

600. The activities alleged in this Complaint had the direct effect of causing funds to be transferred from Allstate to Ameritox for the benefit of the Count I defendants.

601. The Count I defendants participated in the conduct of the Ameritox enterprise through a pattern of racketeering activities.

602. Allstate is a "person," as defined by 18 U.S.C. § 1961(3), injured in its business or property by reason of the Count I defendants' fraudulent acts.

603. The Count I defendants' conduct in violation of 18 U.S.C. § 1962(c) was the direct and proximate cause of Allstate's injury.

604. Allstate is in the business of writing insurance and paying claims.

605. Insurance fraud schemes like the one detailed herein have a deleterious impact on Allstate's overall financial well-being and adversely affect insurance rates.

606. By virtue of the Count I defendants' violations of 18 U.S.C. § 1962(c), Allstate is entitled to recover from them three times the damages sustained by reason of the claims submitted, caused to be submitted, or known to be submitted, by them, and others acting in concert with them, together with the costs of suit, including reasonable attorney's fees.

COUNT II
VIOLATIONS OF 18 U.S.C. § 1962(d)
Against Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman

607. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

608. Ameritox constitutes an enterprise, as defined in 18 U.S.C. § 1961(4), engaged in, and the activities of which affect, interstate commerce.

609. Defendants Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman ("Count II defendants") conspired with each other to violate 18 U.S.C. § 1962(c) through the facilitation of the operation of Ameritox.

610. The Count II defendants each agreed to further, facilitate, support, and/or operate the Ameritox enterprise.

611. As such, the Count II defendants conspired to violate 18 U.S.C. § 1962(c).

612. The purpose of the conspiracy was to obtain No-Fault payments from Allstate on behalf of Ameritox even though Ameritox was not eligible to collect No-Fault payments by virtue of its unlawful conduct.

613. The Count II defendants were aware of this purpose and agreed to take steps to meet the conspiracy's objectives, including the creation and submission to Allstate of insurance claims and legal documents containing material misrepresentations and/or material omissions.

614. Allstate has been injured in its business and property by reason of this conspiratorial conduct whereas Allstate has been induced to make No-Fault claim payments as a result of the Count II defendants' unlawful conduct described herein.

615. By virtue of this violation of 18 U.S.C. § 1962(d), the Count II defendants are jointly and severally liable to Allstate and Allstate is entitled to recover from each three times the damages sustained by reason of the claims submitted by or on behalf of the Count II defendants, and others acting in concert with them, together with the costs of suit, including reasonable attorney's fees.

COUNT III
NEW YORK COMMON LAW FRAUD
Against All Defendants

616. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

617. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the New York No-Fault Law and was entitled to collect benefits thereunder.

618. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

619. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the New York No-Fault Law would be submitted to Allstate.

620. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the New York No-Fault Law.

621. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

622. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the State of New York, Allstate has been damaged as previously described herein and as set out in Exhibit 40.

COUNT IV
NEW JERSEY COMMON LAW FRAUD
Against All Defendants

623. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

624. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the New Jersey No-Fault Law and was entitled to collect benefits thereunder.

625. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

626. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the New Jersey No-Fault Law would be submitted to Allstate.

627. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the New Jersey No-Fault Law.

628. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance

claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

629. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the State of New Jersey, Allstate has been damaged as previously described herein and as set out in Exhibit 41.

COUNT V
MICHIGAN COMMON LAW FRAUD
Against All Defendants

630. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

631. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the Michigan No-Fault Law and was entitled to collect benefits thereunder.

632. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

633. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the Michigan No-Fault Law would be submitted to Allstate.

634. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the Michigan No-Fault Law.

635. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

636. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the State of Michigan, Allstate has been damaged as previously described herein and as set out in Exhibit 42.

COUNT VI
PENNSYLVANIA COMMON LAW FRAUD
Against All Defendants

637. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

638. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the Pennsylvania No-Fault Law and was entitled to collect benefits thereunder.

639. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

640. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the Pennsylvania No-Fault Law would be submitted to Allstate.

641. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the Pennsylvania No-Fault Law.

642. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

643. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the Commonwealth of Pennsylvania, Allstate has been damaged as previously described herein and as set out in Exhibit 43 (PA Damages Chart).

COUNT VII
FLORIDA COMMON LAW FRAUD
Against All Defendants

644. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

645. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the Florida No-Fault Law and was entitled to collect benefits thereunder.

646. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

647. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing

that non-compensable claims for payment under the Florida No-Fault Law would be submitted to Allstate.

648. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the Florida No-Fault Law.

649. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

650. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the State of Florida, Allstate has been damaged as previously described herein and as set out in Exhibit 44.

COUNT VIII
KENTUCKY COMMON LAW FRAUD
Against All Defendants

651. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

652. The scheme to defraud Allstate perpetrated by Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman was dependent upon a succession of material misrepresentations of fact that Ameritox was actually and lawfully rendering medically necessary urine drug testing in compliance with the Kentucky No-Fault Law and was entitled to collect benefits thereunder.

653. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in section VIII *supra*.

654. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the Kentucky No-Fault Law would be submitted to Allstate.

655. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the Kentucky No-Fault Law.

656. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

657. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the Commonwealth of Kentucky, Allstate has been damaged as previously described herein and as set out in Exhibit 45.

COUNT IX
VIOLATIONS OF NEW JERSEY INSURANCE FRAUD PREVENTION ACT
(N.J. STAT. ANN. 17:33A-1, *et seq.*)
Against All Defendants

658. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

659. The New Jersey Insurance Fraud Prevention Act, N.J. Stat. Ann 17:33A-1, *et seq*. ("New Jersey Fraud Act"), provides in relevant part that "[a] person or practitioner violates this act if he:

> (1) Presents or causes to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy or the "Unsatisfied

> Claim and Judgment Fund Law," P.L.1952, c.174 (C.39:6-61 *et seq*.), knowing that the statement contains any false or misleading information concerning any fact or thing material to the claim; or
>
> (2) Prepares or makes any written or oral statement that is intended to be presented to any insurance company, the Unsatisfied Claim and Judgment Fund or any claimant thereof in connection with, or in support of or opposition to any claim for payment or other benefit pursuant to an insurance policy or the "Unsatisfied Claim and Judgment Fund Law," P.L.1952, c.174 (C.39:6-61 *et seq*.), knowing that the statement contains any false or misleading information concerning any fact or thing material to the claim; or
>
> (3) Conceals or knowingly fails to disclose the occurrence of an event which affects any person's initial or continued right or entitlement to (a) any insurance benefit or payment or (b) the amount of any benefit or payment to which the person is entitled; . . . ."

660. Ameritox presented, and Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman caused to be presented, to Allstate false and misleading statements regarding the fact of, necessity of, and proper charge for the urine drug testing purportedly provided to Allstate claimants, including those specific misrepresentations discussed in section VIII *supra*.

661. Ameritox prepared, and Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman caused to be prepared, false and misleading statements regarding the fact of, necessity of, and proper charge for the urine drug testing purportedly provided to Allstate claimants, including those specific misrepresentations discussed in section VIII *supra*.

662. Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman concealed and knowingly failed to disclose that Ameritox was not entitled to insurance benefit proceeds from Allstate because the defendants engaged in a pattern and practice of (1) billing for medically unnecessary, unreasonable, excessive,

and duplicative urine drug testing, and (2) employing fraudulent billing practices, including unbundling.

663. Each HICF submitted to Allstate constitutes a "statement," as defined by the New Jersey Fraud Act.

664. Each HICF submitted to Allstate was prepared and presented with the knowledge that it contained false and misleading information regarding the fact of, necessity of, and charge for urine drug testing that was not performed as claimed.

665. The defendants utilized their superior knowledge and expertise of clinical laboratory urine drug testing to conceal their fraudulent misrepresentations and their pervasive fraud.

666. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that were not compensable under New Jersey's No-Fault Law.

667. Allstate reasonably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to New Jersey No-Fault insurance claims and in incurring expenses related to the investigation, adjustment, and processing of claims submitted by the defendants.

668. As a direct and proximate result of the defendants' fraudulent misrepresentations and acts arising from the State of New Jersey, Allstate has been damaged as previously described herein and as set out in Exhibit 41.

COUNT X
VIOLATIONS OF PENNSYLVANIA INSURANCE FRAUD STATUTE
(18 Pa. Cons. Stat. § 4117)
Against All Defendants

669. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

670. The Pennsylvania Insurance Fraud statute, 18 Pa. Cons. Stat. § 4117(a), provides in relevant part that "[a] person commits an offense [of insurance fraud] if the person does any of the following:

> * * *
>
> (2) Knowingly and with the intent to defraud any insurer or self-insured, presents or causes to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning and fact or thing material to the claim.
>
> (3) Knowingly and with the intent to defraud any insurer or self-insured, assists, abets, solicits or conspires with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim, including information which documents or supports an amount claimed in excess of the actual loss sustained by the claimant.
>
> * * *
>
> (5) Knowingly benefits, directly or indirectly, from the proceeds derived from a violation of this section due to the assistance, conspiracy or urging of any person. . . ."

671. Allstate, and each plaintiff individually, is an "insurer" and "insurance company" within the meaning of the Pennsylvania Insurance Fraud statute.

672. Each HICF submitted to Allstate constitutes a "statement" within the meaning of the Pennsylvania Insurance Fraud statute.

673. The Pennsylvania Insurance Fraud statute permits "[a]n insurer damaged as a result of a violation of this section [to] sue therefor in any court of competent jurisdiction to recover compensatory damages, which may include reasonable investigation expenses, costs of suit and attorney fees. An insurer may recover treble damages if the court determines that the defendant has engaged in a pattern of violating this section." 18 Pa. Cons. Stat. § 4117(g).

674. Ameritox knowingly presented, and Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman knowingly caused to be presented, to Allstate false and misleading statements concerning the fact of, necessity of, and proper charge for the urine drug testing purportedly provided to Allstate claimants, including those specific misrepresentations discussed in section VIII *supra*.

675. Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman knowingly assisted, abetted and conspired with one another to prepare false and misleading statements concerning the fact of, necessity of, and proper charge for the urine drug testing purportedly provided to Allstate claimants, including those specific misrepresentations discussed in section VIII *supra*.

676. Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman knowingly benefitted from the proceeds derived from their above-itemized violations of the Pennsylvania Insurance Fraud statute, including those specific proceeds set out in Exhibit 43.

677. Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman engaged in a pattern and practice of submitting false and misleading statements to Allstate, and conspiring to do the same, for the purpose of obtaining insurance proceeds to which they were not entitled.

678. Each HICF and medical document submitted to Allstate was prepared with the knowledge that it contained false and misleading information regarding the fact of, necessity of, and charge for urine drug testing that was not performed as claimed.

679. The defendants utilized their superior knowledge and expertise of clinical laboratory urine drug testing to conceal their fraudulent misrepresentations and their pervasive fraud.

680. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that were not compensable under Pennsylvania's No-Fault Law.

681. Allstate reasonably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to Pennsylvania No-Fault insurance claims and in incurring expenses related to the investigation, adjustment, and processing of claims submitted by the defendants.

682. As a direct and proximate result of the defendants' fraudulent misrepresentations and acts arising from the Commonwealth of Pennsylvania, Allstate has been damaged as previously described herein and as set out in Exhibit 43.

COUNT XI
VIOLATIONS OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT
(Fla. Stat. § 501.201, *et seq*.)
Against All Defendants

683. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

684. The Florida Deceptive and Unfair Trade Practices Act states that "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Fla. Stat. § 501.204(1).

685. Ameritox, by and through its officers/managers Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman, were actively engaged in trade and commerce in the State of Florida.

686. Allstate, and each plaintiff individually, is a "consumer," as defined in Fla. Stat. § 501.203(7).

687. Ameritox, Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman engaged in unfair and deceptive acts and practices, including seeking benefits under Florida's No-Fault Law for urine drug testing that was (1) medically unnecessary, (2) duplicative, and (3) billed using fraudulent practices.

688. The defendants made numerous fraudulent misrepresentations to induce Allstate to tender No-Fault payments to them, including those specific misrepresentations discussed in section VIII *supra*.

689. The defendants' conduct, detailed in the within Complaint, is unfair because it offends the established policy of the State of Florida and is illegal, immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers like Allstate.

690. The defendants' conduct, detailed in the within Complaint, is deceptive because it is based upon representations, omissions, and other acts and practices that are likely to mislead consumers, including Allstate, acting reasonably under the circumstances to the consumer's detriment.

691. Allstate has been damaged as a direct and proximate result of the defendants' deceptive and unfair acts and practices, including those specific payments itemized in Exhibit 44 that Allstate was induced to pay by the defendants' acts and practices.

COUNT XII
MICHIGAN PAYMENT UNDER MISTAKE OF FACT
Against Ameritox, Ltd.

692. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

693. Allstate paid the amounts described herein and itemized in Exhibit 42 under a misunderstanding, misapprehension, error, fault, or ignorance of material facts, namely, the scheme to defraud Allstate by misrepresenting the necessity of urine drug testing allegedly provided by Ameritox.

694. Allstate sustained damages by paying under a mistake of fact the claims submitted by, or on behalf of, Ameritox that misrepresented the reasonableness, necessity, and lawfulness of the urine drug testing allegedly rendered by Ameritox.

695. Ameritox would be unjustly enriched if permitted to retain the payments made to it under the Michigan No-Fault Statute by Allstate under a mistake of fact.

696. Allstate is entitled to restitution from Ameritox for all monies paid to and/or received by Ameritox from Allstate, as set out in Exhibit 42.

COUNT XIII
NEW YORK UNJUST ENRICHMENT
Against Ameritox, Ltd.

697. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

698. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 40, in response to the claims submitted, or caused to be submitted, by the defendants under New York's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

699. Allstate's payments constitute a benefit which Ameritox aggressively sought and voluntarily accepted.

700. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

701. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

702. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XIV
NEW JERSEY UNJUST ENRICHMENT
Against Ameritox, Ltd.

703. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

704. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 41, in response to the claims submitted, or caused to be submitted, by the defendants under New Jersey's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

705. Allstate's payments constitute a benefit which Ameritox aggressively sought and voluntarily accepted.

706. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

707. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

708. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XV
MICHIGAN UNJUST ENRICHMENT
Against Ameritox, Ltd.

709. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

710. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 42, in response to the claims submitted, or caused to be submitted, by the defendants under Michigan's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

711. Allstate's payments constitute a benefit which Ameritox aggressively sought and voluntarily accepted.

712. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

713. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

714. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XVI
PENNSYLVANIA UNJUST ENRICHMENT
Against Ameritox, Ltd.

715. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

716. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 43, in response to the claims submitted, or caused to be submitted, by the defendants under Pennsylvania's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

717. Allstate's payments constitute a benefit which Ameritox aggressively sought and voluntarily accepted.

718. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

719. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

720. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XVII
FLORIDA UNJUST ENRICHMENT
Against Ameritox, Ltd.

721. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

722. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 44, in response to the claims submitted, or caused to be submitted, by the defendants under Florida's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

723. Allstate's payments constitute a benefit which Ameritox aggressively sought, voluntarily accepted, and appreciated.

724. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

725. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

726. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XVIII
KENTUCKY UNJUST ENRICHMENT
Against Ameritox, Ltd.

727. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

728. Allstate paid monies to Ameritox, including those amounts itemized in Exhibit 45, in response to the claims submitted, or caused to be submitted, by the defendants under Kentucky's No-Fault Laws in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

729. Allstate's payments constitute a benefit which Ameritox aggressively sought and voluntarily accepted.

730. Ameritox wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

731. Ameritox has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

732. Ameritox's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT XIX
DECLARATORY RELIEF PURSUANT TO 28 U.S.C. §2201
Against Ameritox, Ltd.

733. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 587 set forth above as if fully set forth herein.

734. Ameritox routinely billed for medically unnecessary urine drug testing with respect to the patients at issue in this Complaint.

735. Pursuant to the No-Fault laws of New York, New Jersey, Michigan, Pennsylvania, Florida, and Kentucky, providers like Ameritox can only seek reimbursement for services that were medically necessary.

736. Allstate is not obligated to pay insurance proceeds for any services that were unnecessary.

737. Where a claimant and/or assignee (such as Ameritox) is unable to show that an expense has been incurred for a reasonably necessary product or service arising out of a motor vehicle accident, there can be no finding of a breach of the insurer's duty to pay, and thus no finding of liability with regard to that expense.

738. Ameritox continues to submit claims under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law to Allstate for unnecessary services and other claims remain pending with Allstate.

739. Accordingly, Allstate requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that Ameritox provided medically unnecessary drug testing that is not compensable under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law.

740. Allstate further requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that Ameritox, at all relevant times, was engaged in a fraudulent scheme whereby it billed for medically unnecessary urine drug testing and submitted fraudulent billing charges for the same to Allstate.

741. As such, Allstate requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that Ameritox has no standing to submit, pursue, or receive assigned No-Fault benefits from Allstate.

XII. DEMAND FOR RELIEF

WHEREFORE, plaintiffs Allstate Insurance Company, Allstate Indemnity Company, Allstate Property and Casualty Insurance Company, Allstate New Jersey Insurance Company, Allstate New Jersey Property and Casualty Insurance Company, Allstate Fire and Casualty Insurance Company, Encompass Indemnity Company, Encompass Home and Auto Insurance Company, and Encompass Insurance Company of New Jersey respectfully request that a judgment enter in their favor, as follows:

COUNT I
VIOLATIONS OF 18 U.S.C. § 1962(c)
Against Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman

(a) AWARD Allstate its actual and consequential damages against the defendants jointly and severally in an amount to be determined at trial;

(b) AWARD Allstate treble damages pursuant to 18 U.S.C. § 1964, together with interest, costs, and attorney's fees;

(c) GRANT Allstate injunctive relief enjoining the defendants from engaging in the wrongful conduct alleged in the within Complaint; and

(d) GRANT all other relief this Court deems just and proper.

COUNT II
VIOLATIONS OF 18 U.S.C. § 1962(d)
Against Ronald C. Backer, Ph.D., Harry L. Leider, M.D., A. Scott Walton, Ancelmo E. Lopes, and Jay B. Zimmerman

(a) AWARD Allstate its actual and consequential damages against the defendants jointly and severally in an amount to be determined at trial;

(b) AWARD Allstate treble damages pursuant to 18 U.S.C. § 1964, together with interest, costs, and attorney's fees;

(c) GRANT Allstate injunctive relief enjoining the defendants from engaging in the wrongful conduct alleged in the within Complaint; and

(d) GRANT all other relief this Court deems just and proper.

COUNT III
NEW YORK COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT IV
NEW JERSEY COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT V
MICHIGAN COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT VI
PENNSYLVANIA COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT VII
FLORIDA COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT VIII
KENTUCKY COMMON LAW FRAUD
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and

(c) GRANT all other relief this Court deems just and proper.

COUNT IX
VIOLATIONS OF NEW JERSEY INSURANCE FRAUD PREVENTION ACT
(N.J. STAT. ANN. 17:33A-1, *et seq.*)
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate treble damages pursuant to N.J. Stat. Ann. 17:33A-7(b);

(c) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' fraudulent conduct and attorney's fees pursuant to N.J. Stat. Ann. 17:33A-7(a); and

(d) GRANT all other relief this Court deems just and proper.

COUNT X
VIOLATIONS OF PENNSYLVANIA INSURANCE FRAUD STATUTE
(18 Pa. Cons. Stat. § 4117
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate treble damages pursuant to 18 Pa. Cons. Stat. § 4117(g);

(c) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' fraudulent conduct and attorney's fees pursuant to 18 Pa. Cons. Stat. § 4117(g); and

(d) GRANT all other relief this Court deems just and proper.

COUNT XI
VIOLATIONS OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT
(Fla. Stat. § 501.201, *et seq*.)
Against All Defendants

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;

(b) AWARD Allstate its costs, including, but not limited to, attorney's fees pursuant to Fla. Stat. § 501.2105(1) and § 501.211(2); and

(c) GRANT Allstate injunctive relief enjoining the defendants from engaging in the unfair and deceptive acts and practices alleged in the within Complaint; and

(d) GRANT all other relief this Court deems just and proper.

COUNT XII
MICHIGAN PAYMENT UNDER MISTAKE OF FACT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT all other relief this Court deems just.

COUNT XIII
NEW YORK UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XIV
NEW JERSEY UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XV
MICHIGAN UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XVI
PENNSYLVANIA UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XVII
FLORIDA UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XVIII
KENTUCKY UNJUST ENRICHMENT
Against Ameritox, Ltd.

(a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and

(b) GRANT any other relief this Court deems just and proper.

COUNT XIX
DECLARATORY RELIEF PURSUANT TO 28 U.S.C. §2201
Against Ameritox, Ltd.

(a) DECLARE that Ameritox, Ltd. wrongfully submitted bills for urine drug testing that was not necessary and, therefore, not compensable under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law;

(b) DECLARE that Ameritox, Ltd. wrongfully submitted bills for urine drug testing that was unlawful and, therefore, not compensable under the New York No-Fault Law, New Jersey No-Fault Law, Michigan No-Fault Law, Pennsylvania No-Fault Law, Florida No-Fault Law, and Kentucky No-Fault Law;

(c) DECLARE that the activities of Ameritox, Ltd. detailed herein were fraudulent;

(d) DECLARE that Allstate has no obligation to pay pending and/or previously-denied No-Fault insurance claims submitted by Ameritox, Ltd.; and

(e) GRANT all other relief this Court deems just and proper.

XIII. JURY TRIAL DEMAND

The plaintiffs hereby demand a trial by jury on all claims.

[SIGNATURE PAGE FOLLOWS]

Respectfully Submitted,

SMITH & BRINK, P.C.

/s/ Richard D. King, Jr.

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